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(54) A system for preparing a fluid intented for a medical procedure by mixing at least one concentrate in powder form with water and a cartridge intended to be used in said system.

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US-A- 3 560 380

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Description

FIELD OF THE INVENTION

The present invention relates to a system for preparing a fluid intended for a medical procedure and, more particularly, to a system for preparing such a fluid by mixing of at least one concentrate in powder form with water. The system of the present invention is intended, in particular, for the preparation of fluids for use in connection with medical procedures such as hemodialysis, hemodiafiltration and hemofiltration. For instance, the system of the present invention may be used in connection with the preparation of a dialysis fluid for use in connection with hemodialysis, as well as used for preparation of replacement fluids used in connection with hemofiltration or hemdiafiltration. To those skilled in the art, it will be apparent moreover that the system of the present invention can be used in connection with other medical procedures or treatment where a fluid suitable for the treatment is obtained from mixing of water with at least one concentrate in powder form, such as, for example, the production of flushing fluid for cleaning of wounds and the like.

The invention relates also to a cartridge intended to be used in the above system, a method of making such a cartridge and the use of a charge of concentrate in such a cartridge.

BACKGROUND OF THE INVENTION

In hemodialysis operations, the blood of a patient suffering from impaired kidney function is conducted along one side of a permeable membrane in a dialyzer device, at the same time as dialysis fluid is conducted along the opposite side of the same membrane. The poisons or other waste substances that are to be removed from the blood pass with the help of diffusion from the blood of the patient to the dialysis fluid through the permeable membrane. Normally, a certain amount of fluid, primarily water, is also withdrawn from the blood so as to bring about a lowering of the weight of the patient.

Hemodiafiltration differs from hemodialysis first and foremost in that a more permeable filter membrane is utilized. Consequently, greater ultrafiltration or withdrawal of fluid from the blood is obtained, which makes it necesary for a part of the ultrafiltrate removed to be replaced by a replacement fluid. Hemofiltration differs from hemodialysis and hemodiafiltration is that no dialysis fluid is utilized on the opposite side of the permeable membrane along which the blood is conducted. Instead, with the help of a filter, a large quantity of ultrafiltrate is withdrawn from the blood across the filter membrane, which has to be replaced at least partly by a corresponding quantity of replacement fluid.

Different types of control systems are normally used for hemodialysis, hemodiafiltration and hemofitration operations, respectively. However, they all have in common that at least one concentrate fluid is mixed with pure water in order to produce either the dialysis fluid in connection with hemodialysis operations, or the replacement fluids in connection with hemodiafiltration and hemofiltration operations. Normally, the concentrate to be mixed with water is prepared in centralized preparation plants and is then transferred to the point of treatment in large kegs or other containers. Alternatively, the concentrate may be prepared directly on the spot in large tanks or the like before the treatment is to be started. Thus, in either instance, the concentrate to be used in the medical treatment is prepared in the form of a solution prior to actual use in connection with the medial treatment. At the time of treatment, the concentrate solution is then mixed with water to provide the desired prepared solution for the particular medical treatment.

Examples of previously used concentrates, in either powder or liquid form, for use in preparing such prior art concentrate solutions may be found, for instance, in US Patent No 3 560 380; US Patent No 4 404 192; European Patent Specification EP-B1-0 022 922; European Patent Application EP-A1-0 034 916; European Patent Applications EP-A2-C 160 272 and EP-A1-0 177 614; and PCT Publication No WO 85/03435. Further, US Patent No 4 158 034 describes an example of how such concentrate solutions prepared beforehand can be used in the preparation of a solutions suitable for dialysis operations.

Major problems can arise with such prior art types of concentrate solutions prepared prior to their utilization in connection with medical procedures due to the fact that certain concentrates do not always remain stable and/or bacteria-free if prepared in large quantities beforehand. For instance, precipitation may occur either during the transport of concentrate solutions from centralized preparation plants, or even in the aforementioned large tanks or the like before actual treatment is to begin. Furthermore, preparation of concentrate solutions before actual usage in connection with medical treatment can result in bacteria growth if allowed to stand for substantial periods of time.

Reference is also being made to the International PCT-application WO 86/03416 disclosing an apparatus and a method for solving a concentrate which may be in powder form. No means are, however,

described for the control of the concentrate of the prepared solution.

SUMMARY OF THE INVENTION

The present invention is directed to a system which overcomes or minimizes the afore mentioned difficulties and problems of the prior art. Said system is defined in the following claims 1-39. The above mentioned cartridge according to the invention is defined in the claims 40-47, the above mentioned method in claims 48-57 and the above mentioned use in claims 58-65.

More particularly, in accordance with one aspect of the present invention, a primary or first fluid conducting means is provided having one end communicating with a source of water for withdrawing water from the source and a second end for delivering a prepared solution. A concentrate fluid circuit includes a second fluid conducting means which communicates with the source of water and with an inlet to the vessel containing the concentrate in powder form for introducing water from the source of water into the vessel to produce a concentrate fluid containing dissolved powder concentrate and water, and third fluid conducting means which communicates with the outlet of the vessel and with a mixing point in the first fluid conducting means intermediate the first and second ends thereof for conducting the produced concentrate fluid from the vessel into the first fluid conducting means to be mixed with water being conducted therethrough, to thereby produce the prepared solution for delivery to the second end of the first fluid conducting means. Measuring means are provided in the first fluid conducting means downstream of the mixing point for measuring the composition of prepared solution obtained by mixing of the produced concentrate fluid and water being conducted through the first fluid conducting means, and flow regulating means are provided in the third fluid conducting means which is responsive to the measuring means for controlling the flow of concentrate fluid from the vessel.

In accordance with another aspect of the present invention, the system also includes a source of second concentrate fluid, and fourth fluid conducting means having a first end communicating with the source of second concentrate fluid and a second end communicating with primary or first fluid conducting means at a second mixing point intermediate the first and second ends thereof for introducing the second concentrate fluid into the primary fluid conducting means to be mixed with fluid being conducted therethrough to produce the prepared solution downstream of the first and second mixing points, the prepared solution thus being comprised of first concentrate fluid produced by conducting water from the source of water into the vessel containing the concentrate in powder form and second concentrate fluid from the source thereof, both of which are mixed with water withdrawn from the source of water through the primary fluid conducting means.

In accordance with a still further aspect of the present invention, the system includes first and second vessels each containing a concentrate in powder form, the two concentrates being different from one another. The two vessels are adapted to be connected in the concentrate fluid circuit through the use of first and second connection means. The first connection means is provided at a first location in the concentrate fluid circuit for connecting the first vessel to the concentrate fluid circuit so as to introduce fluid containing water from the source of water into the first vessel to dissolve the first concentrate therein and to withdraw the dissolved first concentrate therefrom, and the second connection means is provided at a second location in the concentrate fluid circuit for connecting the second vessel to the concentrate fluid circuit so as to introduce fluid containing water from the source of water into the second vessel to dissolve the second concentrate and to withdraw fluid containing the dissolved second concentrate from the second vessel. The first and second connection means are different from one another so that the first vessel is only connectable by the first connection means to the concentrate fluid circuit at the first location, and the second vessel is only connectable by the second connection means to the concentrate fluid circuit at the second location. Conveniently, in accordance with a preferred embodiment, the first and second connection means comprise first and second holders, with the first holder being configured to only hold a vessel having the configuration of the first vessel, and the second holder being configurated to only hold a vessel having the configuration of the second vessel.

In accordance with another aspect of the present invention, the vessel containing the concentrate in powder form includes an inlet at the top thereof and an outlet at the bottom thereof, with the vessel being arranged in the concentrate fluid circuit so that water withdrawn from the source of water is introduced into the top of the vessel to produce a concentrate fluid containing dissolved powder concentrate, and so that the produced concentrate fluid is withdrawn from the bottom of the vessel and conducted to the primary fluid conducting means to be mixed with water being conducted therethrough to produce the prepared solution. In this manner, water is conducted through the vessel from the top thereof to the bottom thereof to thereby maintain and provide a relatively constant concentration level of dissolved powder concentrate

being introduced into the primary fluid conducting means.

With the system of the present invention, the solution or fluid for the medical treatment can thus be prepared directly at the point of treatment and substantially at or just prior to treatment beginning. Such a system in accordance with the present invention thus avoids the necessity of preparing large quantities of concentrate solutions in liquid form, which would otherwise result in some of the concomitant problems mentioned above.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention can be more fully appreciated with reference to the following detailed description, which refers to the attached drawings in which:

FIGS. 1-4 illustrate four alternative embodiments of the system in accordance with the present innvention for preparing a fluid for a medical procedure by mixing of a concentrate in powder form with water.

FIG. 5 illustrates a further alternative arrangement for the system of the present invention in which the fluid is prepared starting with one concentrate in powder form and a second concentrate in liquid form.

FIG. 6 illustrates a still further arrangement for the system in accordance with the present invention which again utilizes a concentrate in powder form and a concentrate in liquid form, the system of FIG. 6 being particularly adapted for use in connection with a hemodialysis-type of treatment.

FIG. 7 illustrates a cartridge intended to be used in any of the alternative system arrangements shown in FIGS. 1-6, the cartridge being shown mounted in a holder therefor.

FIG. 8 illustrates a still further arrangement for the system in accordance with the present invention in which two different concentrates in powder form are utilized in connection with a further concentrate in liquid form for preparing a fluid for a medical procedure.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings, wherein like reference characters represent like elements, there is shown various alternative arrangements for systems in accordance with the present invention for preparing a fluid for a medical procedure by mixing of at least one concentrate in powder form with water. As the system of the present invention is intended, in particular, for the preparation of dialysis fluids for hemodialysis operations, the system will be described mainly with reference to such an operation. However, it will be appreciated by those skilled in the art that, with minor modifications, the system of the present invention may also be used for the preparation of replacement fluids used in connection with hemofiltration and/or hemodiafiltration operations as well. Still further, to those skilled in the art, it will be apparent that the system in accordance with the present invention can also be used in connection with other medical treatments or procedures.

In connection with hemodialysis operations, the dialysis fluid in accordance with the present invention (as well as replacement fluids for hemodiafiltration and hemofiltration operations) typically may comprise a purified solution containing bicarbonate, such as sodium bicarbonate, together with salt compound such as sodium chloride or, optionally, other alkali or other alkali earth chlorides. With such dialysis solutions containing bicarbonate, there is a risk of precipitation of the bicarbonate, particularly in such instances where the dialysis fluid with bicarbonate is prepared at central processing plants or in large quantities at a treatment facility. The system in accordance with the present invention minimizes such problems of precipitation and/or risk of bacteria growth by preparing the fluid for medical treatment by mixing of at least one concentrate in powder form with water substantially at the time of treatment.

Referring now to FIG. 1, there is shown one arrangement for the system in accordance with the present invention in which there is provided a primary fluid conduit or duct 1 which originates from a suitable source of water, such as a liquid reservoir 2. As is known, the liquid reservoir 2 includes an inlet 15 for introduction of pure water thereinto, for example, from a reverse osmosis unit. The main conduit 1 is provided with a throttling mechanism or device 3, a pressure gauge 4, a pump 5 and a deaerating device 6. The deaeration device 6 typically is provided with an air outlet 16. This outlet may be in direct communication with the atmosphere, but, preferably, is in communication with a discharge via a suction pump (not shown). The main duct 1 includes an outlet 17 for the prepared solution obtained in the manner described more fully hereinbelow. The outlet 17 for the prepared solution may, for example, be passed directly to one side of a dialyzer unit.

The arrangement thus far described, including the components thereof, is well-known in prior art systems for mixing of purified water with a previously prepared liquid concentrate to prepare a fluid for a medical procedure or treatment. Typically, in such prior art systems, the previously prepared liquid

concentrate is introduced into the main conduit leading from the reservoir at a point upstream of the pump therein so that the pump will draw liquid concentrate from its source. This, for example, is shown in the system disclosed in U.S. Patent No. 4,158,034, which is hereby incorporated by reference.

In accordance with the present invention, the system also includes a concentrate fluid circuit which, for example, may be comprised of a fluid conduit or duct 8 which orginates at one end from the liquid reservoir 2, such as by means of a suction nozzle 9 which has been inserted thereinto. The other end of the concentrate fluid duct 8 joins the main fluid line 1 at a mixing point 7 which is intermediate the reservoir 2 and the outlet end 17 of the main line 1. The concentrate fluid conduit 8 includes therein a column or vessel 10 which contains a concentrat 11 in powder form arranged between two particle filters 12. In operation, a portion of the water in the reservoir 2 is drawn off through the concentrate fluid circuit 8 and is introduced into the top of the column or vessel 10 to be conducted downwardly toward the bottom thereof. The concetrate line 8 and column 10 are suitably dimensioned in such a manner that as the water drawn into the concentrate fluid circuit 8 is conducted downwardly through the column 10, a substantially saturated solution of the powder concentrate in water is obtained, to thus produce a concentrate fluid which is then conducted from the column 10 and introduced into the main line 1 at mixing point 7. In this regard, a flow regulating device 13 is provided in the portion of the concentrate fluid conduit 8 intermediate the column 10 and mixing point 7 for controlling the flow of the produced concentrate solution from the column 10 into the main line 1. A conductivity meter or other measuring device 14 is provided in the main line 1 downstream of the mixing point 7 for monitoring the composition of the prepared solution and for then controlling the flow regulating device 13. In this manner, it is possible to accurately control the ultimate mixture of produced fluid concentrate with the water being conducted from the reservoir 2 through the main line 1, even if the concentrate in powder form were to dissolve to different extents or degrees of saturation by virtue of the water being conducted through the concentrate fluid circuit 8. Instead of a conductivity measurement, the measuring device 14 could measure a different property or parameter, such as temperature, pH, or even some other parameter.

The flow regulating device 13 may conveniently comprise a simple adjustable throttling device as shown in FIG. 1. This is advantageous in that it results in a simple overall design for the system since a single pump 5 can be employed for withdrawing water from the reservoir for both the main flow through line 1 and for production of the concentrate fluid in fluid conduit 8. Specifically, by arranging the pump 5 for the suction of water in the main line 1 downstream of the mixing point 7, the pump 5 serves to withdraw water from the reservoir 2 partly through the main line 1, and partly indirectly form the same source via the concentrate fluid circuit 8. Further, with the throttling device 3 provided in the main line 1 between the source of water and the mixing point 7, and the deaerator device 6 is located in the main duct downstream of the pump 5, as shown in FIG. 1, the same pump 5 can also be used for deaeration of the prepared fluid. For the preparation of dialysis fluid, the pump 5 is operative to handle flow rates up to at least 500 ml/min, and more preferably, up to approximately 1,000 ml/min, in the main line 1 downstream of mixing point 7, whereas the flow regulating means 13 is operative to handle flow rates up to approximately 40 ml/min and, in any event, at least 30 ml/min at flow rates of approximately 1,000 ml/min in the main line.

The system shown in FIG. 2 operates in principle in the same manner as that according to FIG. 1. Thus, the same reference numerals have been utilized fo corresponding components as were used with respect to the embodiment shown in FIG. 1. To the extent that any of the components have been modified, such components have been indicated through the use of the letter "a" after the reference numeral.

The system shown in FIG. 2 differes from that according to FIG. 1 mainly through the employment of a mixing pump 13a as the flow regulating device, in place of the throttle device 13 employed in the embodiment of FIG. 1. In this connection, it has been found appropriate to also provide a special deaeration arrangement for the powder concentrate column 10. To this end, a vent opening 18 is provided which is preferably arranged at or near the top of the powder concentrate column or vessel 10. A suction line or duct 19 is connected at one end to the vent 18 at the other end to the concentrate conduit 8 at a point upstream of the suction pump 13a. The suction line 19 also includes a hydrophobic filter 20 therein. In this manner, suction pressure is produced appropriately in the suction line 19 through the aid of the pump 13a which thus facilitates deaeration of the system, especially during start-up. When the column 10 has been totally deaerated, any liquid drawn into the line 19 will be blocked or stopped upon reaching the hydrophobic filter 20 and, thus, liquid will only be withdrawn from the column 10 via the concentrate conduit 8. Should any new air or other gas be formed in the column 10 during operation, this normally would remain in the uppermost part of the column 10, therefore, will not disturb any subsequent measurement. Of course, the system according to FIG. 2 may also include means (not shown) for the deaeration of the main stream being conducted through the primary or main line 1.

The system according to FIG. 3 also corresponds in principle to that illustrated in FIGS. 1 and 2 and,

therefore, the same reference numerals have been used with respect to the same components. Modified components have been indicated through the use of the additional letter "b". The system of FIG. 3 differs from that of FIG. 2 in that the deaeration or suction line 19 has been replaced with a deaeration line 19b which includes a hydrophobic filter 20 arranged therein together with an adjustable throttle device 21. Also, in contrast to the deaeration line 19 shown in FIG. 1, the line 19b does not open directly into the concentrate conduit 8, but rather, communicates with the main line 1 immediately upstream of the pump 5 and downstream of the throttle device 3. In order that the hydrophobic filter 20 should not be subjected to the entire negative deaeration pressure during normal operation, the throttle device 21 preferably is adapted so that it is capable of being closed completely when deaeration of the column 10 has been completed.

FIG. 4 shows a further alternative arrangement for the concentrate powder column 10 and suction duct 19. In this arrangement, the hydrophobic filter 20 has been replaced by or alternatively used in combination with, an expansive body or material 22 provided within the housing therefor, designated by the reference character 20c, which is adapted to expand upon water being drawn into the housing 20c to thus close off further flow therethrough. Thus, with this arrangement, the line 19 is effectively closed after complete deaeration by means of the expansion of the body 22.

Thus, it will be appreciated that in accordance with the embodiments of the system shown in FIGS. 2, 3 and 4, a separate venting arrangement is provided in the column 10. More particularly, the column 10 is provided with a separate vent opening 18 which preferably is arranged at or near the highest point of the column 10. Deaeration of the system is further facilitated through the aid of a suction line 19 originating from the vent opening 18 in the column and preferably provided with a hydrophobic filter or other shut-off device for the fluid. In this manner, any irregular discharge during normal operation of fluid concentrate through the suction line 19 is prevented. Further, the suction duct 19 connected to the vent opening 18 in the column 10 can communicate either with the concentrate conduit 8 or directly with the main line 1. In each instance, such communication should take place appropriately just upstream of the suction pump 13a or 5 installed in the respective conduit 8 or 1.

Further, in accordance with the preferred embodiments of the present invention, it is to be noted that water is introduced into the concentrate powder column 10 at the top of the column 10 and conducted downwardly to the bottom thereof. This is preferably in order to maintain and provide a relatively constant concentration level of dissolved powder concentrate into the primary fluid line 1. However, it should also be appreciated that water withdrawn into the concentrate fluid line 8 could be conducted through the powder column 10 from the bottom toward the top, both in connection with normal operation as well as in connection with initial priming of the system.

Still further, it should be appreciated that the primary fluid line 1 and concentrate fluid line 8 could both be connected directly to a source of water such as a tap water system, for example, by means of a T-coupling, instead of to a reservoir which is supplied with water. Furthermore, it should also be appreciated that the primary fluid line 1 and concentrate fluid line 8 could be connected to different sources of water, although it is preferable that they both be connected to a common source of water such as reservoir 2 as shown in FIGS. 1-4.

In certain instances, the solution for a medical procedure or treatment is to be prepared from more than one concentrate, such as, for example, the dialysis solution disclosed in the aforementioned European patent specification EP-B1-0 022 922. In such situations, in accordance with the present invention, the more stable concentrate may be provided in a liquid form and the less stable concentrate or concentrates provided in powder form. In this regard, FIG. 5 illustrates a modified system in accordance with the present invention for preparing a solution for a medical procedure or treatment in which the solution is prepared from one concentrate in powder form and one concentrate in liquid form. Again, in FIG. 5, the same reference characters have been used as in the remaining figures, but with the added letter "d" being used to designate modified components.

In accordance with the modified system shown in FIG. 5, a suitable reservoir 2 is provided from which fluid for preparing a solution is conducted, on the one hand, via a main or primary conduit 1 and, on the other hand, through a concentrate cicuit or conduit 8d containing a powder concentrate column 10d therein. The concentrate conduit 8d communicates with the main conduit 1 at a mixing point 7. Means for regulating the flow of fluid in the main conduit 1 and for deaeration, respectively, have been indicated by a single rectangle marked 3d, 5d, 6d. A conductivity meter or other measuring device is provided in the main conduit 1, as indicated by the reference numeral 14d. The conductivity meter or other measuring device 14d is adapted to control a flow regulating device 13d provided in the concentrate conduit 8d downstream of the powder concentrate column 10d. If the flow regulating device 13d comprises a throttle, such throttle 13 shown in FIG. 1, the throttle device 3d should be located upstream of the mixing point 7. It will thus be appreciated that the foregoing description of the system according to FIG. 5 substantially corresponds with

the systems described hereinabove with reference to FIGS. 1-4. In the system of FIG. 5, however, a second mixing point 23 is provided downstream of the conductivity meter 14d. At mixing point 23, a second concentrate fluid is introduced into the main duct via a second concentrate conduit or duct 24 which communicates with a source of second concentrate 25, which, in this instance, is in a liquid form. The flow of concentrate through the second concentrate duct 24 is regulated with the aid of a conductivity meter or other measuring device 26 provided in the main conduit 1 and which controls a flow regulating device 27 provided in the second concentrate duct 24. For ultimate monitoring of the prepared solution, a pH meter 28 may be installed in the main conduit 1. If conductivity, pH, temperature, or any other parameter utilized for controlling the flow of concentrates through their respective conduits 8d, 24 do not agree or correspond with the desired value, the prepared fluid is passed via a bypass valve 29 directly to a discharge (not shown). If, on the other hand, all of the parameters are correct or in accordance with their desired values, the prepared solution is passed via valve 30 to the actual point of treatment, for example, a dialyzer.

Thus, it will be appreciated that if two concentratets are to be conducted to the main duct 1 at two separate mixing points 7, 23 in the main conduit 1 for mixing with the fluid being conducted through the main conduit 1, conductivity meters or other measuring devices 14d, 26 for accurate monitoring of the composition of the prepared solution upstream as well as downstream of the second mixing point 23 may appropriately be arranged in the main duct 1 and, in particular, arranged downstream of the respective mixing point 7 with which the concentrate conduit 8d communicates.

FIG. 6 shows a still further modified system in accordance with the principles of the present invention which is particularly intended for use in connection with preparation of a dialysis fluid for use in connection with a hemodialysis operation. Once again, the same reference characters have been used to designate like components, with the added character "e" being included with respect to modified components. The system shown in FIG. 6 is similar to that in accordance with FIG. 5 in that it is used to prepare a solution from two different concentrates, one in liquid form and one in powder form. The system of FIG. 6 differs from FIG. 5, however, with respect to the location the concentrate fluids obtained from the liquid and powder sources are introduced into the main duct or conduit 1.

In accordance with the system of FIG. 6, water for use in preparing the dialysis fluid is introduced to a heating vessel or reservoir 2 for heating the water to the desired temperature. From the heating vessel or reservoir 2, the main part of the water used in preparing the dialysis fluid is conducted from the reservoir 2 through a main or primary conduit 1. In the main conduit 1, the flow is degased by means of a throttle 3e and, a pump 5e and a deaerator 6e, shown together in FIG. 6 as a single rectangle. A liquid concentrate line or duct 24e communicates with the main conduit 1 at a mixing point 23e downstream of the throttle 3e and the rectangle 5e, 6e. The concentrate duct 24e includes a concentrate pump 27e therein which pumps a liquid concentrate from a liquid concentrate container 25e. The conductivity of the mixture after introduction of the liquid concentrate is measured in the main conduit 1 by means of a conductivity meter 26e which controls the pump 27e.

A smaller portion of the water in the reservoir 2 is fed through a concentrate fluid circuit comprised of a concentrate conduit 8e. A column or vessel 10 containing a concentrate in powder form is provided in the concentrate conduit 8e so that, as with the other embodiments discussed hereinabove, the smaller portion of water withdrawn from the reservoir 2 is fed through the column 10 from the top toward the bottom thereof, and from there through a continuation of the concentrate conduit 8e to a concentrate pump 13e. From the pump 13e, the concentrate fluid obtained from the vessel 10 is then conducted to the main conduit 1 at a mixing point 7e where it is mixed with the main flow of water from the reservoir 2, which includes the liquid concentrate therein. The conductivity is thereafter measured once again, utilizing the conductivity meter 14e which controls the pump 13e in the concentrate conduit 8e.

For the ultimate monitoring of the prepared solution, a pH meter 28e and a third conductivity meter 31e are arranged in the main conduit 1 downstream of the second mixing point 7e, but upstream of a bypass valve 29e and a main valve 30e through which the system may be connected to a dialyzer. If the measurements obtained in the main conduit 1 from the conductivity meters 26e, 14e, 31e and/or the pH meter 28e are not in accord with the desired values, the main valve 30e is closed and valve 29e opened. For this purpose, the conductivity meters 26e, 14e, 31e and pH meter 28e are all shown as controlling valves 29e and 30e. Although the various meters for measuring the properties of the fluid being conducted through main conduit 1 preferably control the valves 29e and 30e, it will also be appreciated that it is possible instead to control one or more of the pumps 5e, 13e and 27e to stop the conduction of fluid through the various conduits.

The system shown in FIG. 6 also includes means for initial priming of the system and, in particular, the powder concentrate column, as well as means for disinfection or sterilization of the system. More particularly, downstream of the powder concentrate column 10, there is provided a bypass or priming line

66 connected to the concentrate conduit 8e and the main conduit 1 downstream of the throttle 3e and upstream of the pump/deareator rectangle 5e, 6e. A valve 32 is provided at the point that the priming line 66 is connected to the concentrate conduit 8e. When the system, especially the dry column 10, is to be initially primed with water from the heating vessel or reservoir 2, the valve 32 is opened together with a second valve 33, both controlled by a pressure switch or button 34. The two valves 32, 33 are kept open until water reaches the point 35 where the bypass-line joins the concentrate conduit 8e. Thereafter, the two valves 32, 33 are closed and the water, which is now a concentrate fluid containing dissolved powder concentrate therein, may continue through the concentrate conduit 8e to the pump 13e. An adjustable throttling device 41 may also be provided in the priming line 66 in parallel to the valve 33. This arrangement thus facilitates initial dearation of the system by virtue of air being drawn from the vessel and introduced into the mainline 1 upstream of the dearator 6e.

For disinfection or sterilization of the system, the powder concentrate vessel or column 10 is removed from the concentrate fluid circuit 8e, and the ends of the concentration conduit 8e normally connected to the vessel 10 are instead connected to connection points 36 and 37, respectively, of separate sterilization conduits or lines 40 and 42. The liquid concentrate container 25e is als removed, and the concentrate duct 24e connected to a connection point 38e in fluid communication with the sterilization line 42. Furthermore, the start point 39 of the concentrate conduit 8e, normally connected to the heating vessel or reservoir 2, is instead connected to a source of disinfection liquid (not shown). In this manner, disinfection liquid is fed through the starting branch of the concentrate conduit 8e to the connection point 36 where it is conducted through the sterilization line 40 to the valve 32. From valve 32, the disinfection liquid is conducted either through the valve 33 or through the parallel valve 41, in the nature of an adjustable throttling device, to the main conduit 1. From the main conduit 1, the disinfection liquid then passes through the throttle device 3e, pump 5e and deaerator 6e until it reaches the mixing point 23e. At mixing point 23e, one part of the disinfection liquid is conducted through the concentrae line 24e via pump 27e, which has now been reversed. The concentrate line 24e, now connected to connection point 38e in the sterilization conduit 42, serves to conduct the disinfection liquid through line 42 to the point 37 which is attached to the lower part of the concentrate conduit 8e. From there, the disinfection liquid continues through the concentration conduit 8e via pump 13e and back to the main conduit 1, where it meets the rest of the flow of disinfection liquid being conducted through the main conduit 1 from the mixing point 23e. The disinfection liquid then continues through the main conduit 1 to the end valve 30e.

It will thus be appreciated that the various conduits, deaeration of de-gasing devices, pumps and meters of the system, which are all reusable, can easily be disinfected or sterilized for subsequent treatment operations. This is accomplished simply by removing the sources of concentrate, which are generally designed so as to contain a quantity of concentrate suitable for one treatment operation alone, and connecting the concentrate conduits or lines 8e, 24e normally connected to the concentrate sources 10, 25e to additional disinfectant lines 40, 42 and to a source of disinfection or sterilizing fluid. The additional disinfectant conduits 40, 42 are suitably arranged and connected to the remaining components of the system to insure that disinfection solution is conducted throughout all of the reusable components, namely, the conduit lines 1, 8e, 24e, the various meters 14e, 26e, 28e, 31e, and de-gasing and deaeration devices and pumps 3e, 5e, 6e, 13e, 27e.

Further in accordance with the present invention, the powder concentrate columns or vessels 10 utilized in the various embodiments described hereinabove may conveniently be in th form of a self-contained cartridge containing a quantity of powder concentrate therein suitable for one treatment procedure, the cartridge being totally closed and provided with penetrable membranes at its upper inlet and its lower outlet which are adapted to be penetrated by suitable connection devices for the ends of the conduit in the fluid concentrate circuit 8 or 8d or 8e. Also, preferabely, the cartridge is internally sterile, such as by having been exposed to radiation such as gamma radiation. Fig. 7 shows such a cartridge 10f, as well as a holder 43 therefor, which is specially constructed to accomodate a cartridge of a particular configuration.

As shown in FIG. 7, the cartridge column 10f comprises a closed vessel provided with penetrable membranes 62, 64 at its upper inlet end and its lower outlet end, respectively. Within the cartridge vessel, there is provided a supply of powder concentrate of sufficient quantity so as to be suitable for a single treatment. For instance, in connection with preparation of a dialysis fluid or solution, the concentrate in powder form may conist of sodium bicarbonate material, and the quantity thereof contained in the cartridge would be on the order of magnitude of 400-900 grams and, more preferably, approximately 600 grams. Also, the contents of the cartridge 10f are preferably sterilized, such as by means of gamma radiation.

Further, in order to obtain an even flow of fluid through the powder concentrate vessel or column 10f and, thus, a uniform solution of the powder in the fluid, it has been found that there is a preferable minimum particle size for the powder concentrate. For many materials, and especially bicarbonate materials, it has

been found that the particles of powder should be of a size of at least 100 microns (μ), and preferably larger than 150 microns (μ). A minor blending in of smaller particles may, however, be acceptable. In this regards, a suitable mixture, for example, may be comprised of powder particles having a sixe of between 130 and 500 microns (μ).

The cartridge 10f is adapted to be mounted in a holder 43 provided with a pair of upper and lower swinging arms 44 and 45 mounted on a suitable support structure 60. The arms 44, 45 are provided with spike connectors 46 and 47, respectively, which are intended to penetrate the membranes 62, 64 at the upper inlet and the lower outlet of the closed cartridge vessel 10f. In this regards, the upper inlet and lower outlet of the cartridge 10f are each provided with an outwardly protruding nipple having the penetrable membranes 62, 64 therein, which nipples are adapted to be received in suitable recesses in the arms 44, 45 so that the end of the spike connectors 46, 47 may penetrate same when the arms 44, 45 are swung into essentially horizontal positions to hold the cartridge 10f. In this regards, the spacing between the arms 44, 45 is such as to correspond to the height of the cartridge 10f. The upper or inlet spike 46 is intended to be connected to the conduit in the concentrate fluid circuit 8e which is upstream of the cartridge 10 as shown in FIG. 6, whereas the outlet spike 47 is intended to be attached to the concentrate conduit which is downstream of the cartridge 10 in the fluid concentrate circuit 8e. It will thus be appreciated that connection of the cartridge 10f in the circuit 8e is accomplished relatively easily by moving the arms 44, 45 apart, positioning the cartridge 10f therebetween and then moving the arms 44, 45 into horizontal, parallel, positions so that the spikes 46, 47 penetrate the membranes 62, 64.

When the system in accordance with the present invention is to be sterilized or disinfected, it will be appreciated with reference to FIG. 7 that it is a relatively simple operation to remove the cartridge 10f and to connect the spike 46 to anipple 48 and the spike 47 to a nipple 49 mounted on the support structure 60 for the cartridge 10f. The nipples 48 and 49 correspond to the connection points 36 and 37, respectively, which are schematically shown in FIG. 6.

When an accurate regulation of a plurality of substances which are to be included in a prepared solution for a medical treatment is desired, two or more columns or other vessels 10 of powder concentrates of different types may be arranged in the concentrate fluid circuit 8, for example, one column for each of the principal substances to be included in or mixed with the water for preparation of the prepared solution. In this instance, each of the columns 10 for the respective powder concentrates may be of a distinct configuration, such as, distinct with regard to shape, the manner of connection or some other like manner, so that each column or other vessel 10 of powder concentrate which is to be connected to the system may only be connected at the correct point or location within the system.

Conveniently, this may be accomplished through the use of different size cartridges 10f and different holders 43 of the type shown in FIG. 7 in which the spacing between the arms 44, 45 is different for the respective, different size cartridges 10f containing powder concentrates.

For instance, FIG. 8 schematically shows a still further arrangement for a system in accordance with the present invention in which two different substances in the form of powder concentrates, as well as a liquid concentrate, are used in preparing a solution for a medical treatment. Again, the same reference characters are used in FIG. 8, but with the addition of the character "g" thereafter to indicate modified components. More specifically, the system of FIG. 8 is particularly useful in connection with preparing a dialysis fluid for a dialysis operation which includes two columns or vessels of powder material, one including a bicarbonate material and one including a salt solution, such as sodium chloride, as well as a liquid concentrate such as acid.

As can best be seen in FIG. 8, the two columns $10g_1$ and 10_2 containing powder concentrate are in the form of self-contained cartridges similar to that shown in FIG. 7, except that they are of different sizes. Specifically, cartridge $10g_1$ and $10g_2$ are arranged in parallel to one another in the concentrate fluid circuit 8g so that each will receive a portion of the water directed from the heating vessel or reservoir 2. The water withdrawn from the reservoir 2 through the concentrate fluid circuit 8g flows through the respective cartridges $10g_1$ and $10g_2$ to thus produced two concentrate fluids, each comprised of powder concentrate dissolved in water.

Water is also withdrawn from the heating vessel or reservoir 2 through a main line 1. The concentrate fluids obtained from the two vessels $10g_1$ and $10g_2$ are returned to the main line 1 at two different mixing points, 23g and 7g, respectively, with the mixing points 23g, 7g being separated from one another and with a conductivity meter 26g provided therebetween. Liquid concentrate, such as an acid, may be taken from a suitable container or bag 50 by means of a pump 51 which may be controlled in such a manner that a desired value is obtained in a drip counter 52. The concentrate from the drip counter 52 is conducted to the main line of conduit 1 at a mixing point 23g. At a point 54 intermediate the mixing points 53 and 23g, a further conductivity meter of pH-meter (not shown) may be provided. However, such a meter is not

necessary if the pump 51 for the acid is controlled precisely.

The remainder of the system shown in FIG. 8 corresponds essentially to the system according to FIG. 6, with the exception of the modifications for accommodating two different size powder concentrate cartridges $10g_1$ and $10g_2$. As shown in FIG. 8, the concentrate fluid circuit 8g includes two parallel branch lines $8g_1$ and $8g_2$, with one cartridge $10g_1$ being arranged in one branch line $8g_1$, and the other cartridge $10g_2$ arranged in the other brach line $8g_2$. Conveniently, a holder such as holder 43 shown in FIG. 7 but sized to accomodate cartridge $10g_1$ can be used to hold cartridge $10g_1$ in position in branch line $8g_1$, whereas a larger sized holder can be use to hold cartride $10g_2$ in branch line $8g_2$. In this way, only cartride $10g_1$ can be positioned in line $8g_1$ and only cartridge $10g_2$ positioned in line $8g_2$. This thus provides a degree of protection against improperly connecting the cartridges $10g_1$, $10g_2$ to the system. Of course, different connection means, such as different manners of connecting the conduits to the cartridges $10g_1$, $10g_2$, particular shapes for the cartridges and holders therefor, or other special configurations, could be used for insuring that the cartridges can be connected to the system only at the correct locations.

Branch line $8g_1$ includes a pump 13g therein downstream of cartridge $10g_1$ for conducting concentrate fluid produced in cartridge $10g_1$ to the main conduit 1 at mixing point 7g, whereas brand line $8g_2$ includes a pump 27g therein downstream of cartridge $10g_2$ for conducting concentrate fluid produced in cartridge $10g_2$ to the main conduit 1 at mixing point 23g. A separate priming line 66g is also provided, connected to each of the branch lines $8g_1$, $8g_2$ via means of valves $32g_1$, $32g_2$ downstream of the respective cartridges $10g_1$, $10g_2$ and communicating with mainline 1 intermediate the throttle device 3g and the pump deareator rectangle 5g, 6g. The priming line 66g is for a similar purpose as the priming line 66 shown in FIG. 6.

By way of example, for preparation of a dialysis fluid, the cartridge $10g_1$ may contain a bicarbonate material in powder form, such as sodium bicarbonate, whereas the cartridge $10g_2$ may contain a different concentrate powder form, such as sodium chloride powder. In this instance, the quantity of sodium bicarbonate in cartridge $10g_1$ may be on the order of 400-900 grams and, more preferably, approximately 600 grams, whereas the quantity of sodium chloride in the cartridge $10g_2$ would preferably be on the order of 1,000-3,000 grams and, more preferably, 1,300-2,700 grams and, still more preferably, approximately 1,400 grams. Such cartridges $10g_1$ and $10g_2$ for use in connection with preparation of a dialysis fluid, i.e., a cartridge $10g_1$ containing bicarbonate material and a cartridge $10g_2$ containing sodium chloride material, both in powder form, may also be used in practice, together with a liquid concentrate 50 which contains other substances necessary for the treatment, such as, for example, acid, calcium, potassium, magnesium, glucose, or the like. A suitable composition for the liquid concentrate 50, for example, may be as follows:

CH_3COOH	44.17 g
KCl	36.54 g
$CaCl_2 + 6H_2O$	93.94 g
$MgCl_2 + 6H_2O$	24.92 g
H_2O	210 g
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Total approx.	410 g

The quantities provided in the example hereinabove correspond to that necessary for one treatment operation or procedure, with the quantity of water being determined so that no precipitation should be able to occur during storage at refrigerating cabinet temperature. With a smaller quantity of water, there is a risk of precipitation. In the example above, it will be appreciated that instead of acidic acid, other acids could be

used, such as, for example, hydrochloric acid or citric acid.

Preferably, in the system shown in FIG. 8, suitable restrictions 55 and 56 are provided in the respective branch concentrate lines $8g_1$ and $8g_2$ prior to or upstream of the respective cartridges $10g_1$ and $10g_2$. These restrictions 55, 56 are useful in obtaining a subpressure in the two cartridges $10g_1$, $10g_2$ during initial priming of the circuit $8g_2$. Priming is thereafter stopped, and additional suction of water into the cartridges $10g_1$, $10g_2$ is insured, thus providing a feature of security that water will cover the powder, even if an air cushion is provided at the top of each cartridge $10g_1$, $10g_2$.

Also, preferably air or water detectors are provided so that one can determine if the cartridges $10g_1$, $10g_2$ have been filled with water. Further, the detectors may be used for checking that the cartridges $10g_1$, $10g_2$ did not include any water therein when the system was initially started or primed. Here it should be noted that if a column or cartridge 10 is filled with water and left therein for any period of time, either because the concentrate fluid produced is unused or only partly used, there is a risk that the dry powder, stable in and of itself, may be altered or that bacteria growth may occur within the cartridge or column 10. For this purpose, as shown in FIG. 8, an air or water detector 57 may be provided in the priming line and/or separate detectors 58 and 59 may be arranged directly downstream of the respective cartridges $10g_1$, $10g_2$ for checking whether the cartridges $10g_1$, $10g_2$ contain any water at the start of a treatment operation, i.e., to insure that they have not been partly used previously or, for other reasons, contain liquid therein. Such detectors 57, 58, 59, for example, may be in the form of normally dry electrodes arranged inside the priming and/or branch conduit lines 66g, $8g_1$, $8g_2$, or could even be arranged inside the cartridges or columns $10g_1$, $10g_2$. Alternatively, conductivity meters could be employed in the system which show a deflection only when air included in the system has passed therethrough. Here it should be noted that if the presence of water is detected in the cartridges or columns, suitable alarms can be actuated for insuring that the prepared solution is not delivered to the dialyzer, such as, for example, by closing of the valve 30g and opening of the valve 29g.

Further with respect to the embodiment of the system shown in FIG. 8, it should be noted that the acid from the container 50 may instead be fed into the concentrate line $8g_2$ upstream of the pump 27g, thus providing the advantage that the acid is fed to a line which has a more constant pressure. Here it should be noted that the pressure of the fluid within the main line 1 may vary, whereas, the pressure within the lines $8g_1$, $8g_2$ is more constant. Thus, by such a construction, the risk is less that fluid would be conducted into the tank or container 50, or sucked thereoutof without any suitable control.

Still further, as with the systems of the present invention described by way of the other embodiments hereinabove, an alarm may suitably be provided to protect against an incorrect conductivity value being measured by the various conductivity measuring devices 26g, 14g or 31g or the values measured by the pH meter 28g, or by any other meters. Additionally, an alarm could also be generated if there is an absence of any acid from the container 50 present in the drip counter 52. Conveniently, the container 50 for the acid may comprise a plastic bag which can conveniently be connected to the system by means of a suitable coupling device, such as, for example, that described and shown in U.S. Patent No. 4,636,204. As for the acid pump 51, a volumetric-type pump may be utilized which provides the desired flow of acid through the drip counter 52. Still further, in addition to the arrangement of the acid or liquid concentrate being introduced into the main line 1, the liquid or acid from the container 50 may also be fed to a point in the main line 1 which is downstream of the conductivity meters 14g and 26g, which would provide the advantage that the conductivity meters 14g, 26g would not be influenced by the introduction of acid into the main line 1.

It will thus be apparent from the foregoing description that the present invention provides a system for preparing a fluid intended for a medical procedure by mixing of at least one concentrate in a powder form. The system in accordance with the present invention comprises a reservoir 2 for a source of water, and at least one vessel 10 for containing a concentrate in powder form, and a fluid conducting circuit 8 for withdrawing a small quantity of water from the reservoir 2 and passing same through the vessel 10 containing the concentrate in powder form in order to dissolve the concentrate before it is mixed with the rest of the water withdrawn from the reservoir 2 through a main or primary fluid conducting means 1 downstream of the liquid-containing reservoir 2. In accordance with one aspect of the present invention, measuring means 14 are provided in the primary fluid conduit means 1 downstream of the mixing point 7 for measuring the composition of the prepared solution obtained by mixing of the produced concentrate fluid in the concentrate fluid circuit 8 with water being conducted through the primary conduit 1, and flow regulating means 13 provided in the concentrate fluid circuit 8 downstream of the concentrate vessel 10 which is responsive to the measuring means 13 for controlling the flow of concentrate fluid from the vessel 10.

In accordance with a further aspect of the present invention, a source of second concentrate fluid 25,

$10g_2$ is provided as well, and fluid conducting means 24 are provided for introducing the second concentrate fluid into the primary fluid conducting means 1 at a second mixing point 23 therein to be mixed with the fluid being conducted therethrough to thereby produce a prepared solution downstream of the two mixing points 7, 23, the prepared solution being comprised of a mixture of water with a first concentrate fluid produced by conducting water from the reservoir 2 into the vessel 10, $10g_1$ containing the concentrate in powder form and a second concentrate fluid from the source 25, $10g_2$ thereof. In one embodiment of the present invention, the source of second concentrate fluid comprises a concentrate in liquid form 25, wheras, in a further embodiment of the present invention, the second concentrate fluid is produced by conducting water from the reservoir 2 through a second vessel $10g_2$ containing powdered concentrate therein to dissolve the second powdered concentrate in the water to produce the second concentrate fluid.

In accordance with a still further aspect of the present invention, the vessel 10 containing the concentrate in powder form therein includes an inlet at the top thereof and an outlet of the bottom thereof, with the vessel 10 being arranged in the concentrate fluid circuit 8 so that water withdrawn from the reservoir 2 is introduced into the top of the vessel 10 to produce a concentrate fluid containing dissolved powder concentrate therein, and so that the concentrate fluid is withdrawn from the bottom of the vessel 10 and conducted to the primary fluid conducting means 1 to be mixed with water being conducted therethrough. In this manner, water is conducted through the powder concentrate vessel 10 from the top thereof to the bottom thereof to thereby maintain and provide a relatively constant concentration level of dissolved powder concentrate. Conveniently, the powder concentrate vessel 10 may comprise a normally completely closed cartridge 10f, having penetrable membranes 62, 64 at its inlet and outlet outlets which are adapted to be penetrated upon being connected to the concentrate fluid circuit 8. The cartridge 10f contains a quantity of powder concentrate therein suitable for one treatment procedure. In this manner, for different treatment operations, it is only necessary to connect new cartridges 10 and/or other sources 25, 50 of liquid concentrate to the system, with the remaining components of the system being reusable for different medical procedures or treatments.

As will be readily apparent to those skilled in the art, the present invention may be used in other specific forms without departing from its characteristics. For example, the components included in the system may be varied within wide limits, both with regard to their form and their function. Furthermore, it will be apparent to those versed in the art that the system of the present invention can readily be modified by combinations of one or more powder concentrates, either alone or in further combination with one or more liquid concentrates, for producing a desired prepared solution for a medical procedure or treatment. The preferred embodiments described hereinabove are therefore to be considered as illustrative and not restrictive, the scope of the invention being indicated by the claims rather than the foregoing description, and all changes which come within the meaning or range of the claims are therefore intended to be embraced therein.

Claims

1. A system for preparing a fluid for a medical procedure by mixing of at least one concentrate in powder form with water, said system being characterized by:

a vessel (10) containing a concentrate (11) in powder form consisting of only one single substance;

first fluid conducting means (1) having a first end for communicating with a source (2) of water to withdraw water into said first fluid conducting means and a second end for delivering a prepared solution;

second fluid conducting means (8) having a first end for communicating with a source of water (2) and a second end communicating with an inlet of said vessel (10) for introducing water into said vessel (10) to produce a concentrate fluid containing dissolved powder concentrate in water;

third fluid conducting means (8) communicating with an outlet of said vessel (10) and with a mixing point (7) in said first fluid conducting means (1) intermediate said first and second ends for conducting said concentrate fluid from said vessel (10) into said first fluid conducting means (1) to be mixed with fluid being conducted through said first fluid conducting means (1) to thereby produce a prepared solution in said first fluid conducting means (1) for delivery to said second end of said first fluid conducting means (1);

measuring means (14) in said first fluid conducting means (1) downstream of said mixing point (7) for measuring the composition of the prepared solution obtained by mixing of said concentrate fluid and water in said first fluid conducting means (1); and

flow regulating means (13) in said third fluid conducting means (8) responsive to said measuring means (14) for controlling the flow of said concentrate fluid from said vessel (10).

2. The system of claim 1, further including a common source (2) of water for said first and second fluid conducting means (1,8), said first end of said first fluid conducting means (1) and said second fluid conducting means (8) each communicating with said common source (2) of water.

3. The system of claim 2, wherein said common source (2) of water comprises a reservoir (2) for containing water.

4. The system of claim 1, wherein said measuring means (14) comprises a conductivity measuring device (14).

5. The system of claim 1, wherein said flow regulating means (13) comprises a throttling device (13).

6. The system of claim 3, further including a suction pump (5) arranged in said first fluid conducting means (1) downstream of said mixing point (7) for conducting water from said reservoir (2) through said first fluid conducting means (1) and for conducting water from said reservoir (2) through said second and third fluid conducting means (8,8).

7. The system of claim 6, further including a throttling device (3) arranged in said first fluid conducting means (1) intermediate said reservoir (2) and said mixing point (7), and further including a deaerating device (6) arranged in said first fluid conducting means (1) downstream of said suction pump (5).

8. The system of claim 1, wherein said flow regulating means (13a) comprises a suction pump (13a).

9. The system of claim 1, wherein said inlet of said vessel (10) is at the top thereof and said outlet of said vessel (10) is at the bottom thereof so that water is conducted through said vessel (10) from the top thereof to the bottom thereof to thereby maintain a relatively constant concentration level of dissolved powder concentrate in said third fluid conducting means (8).

10. The system of claim 1, wherein said vessel (10) includes a vent opening (18) therein arranged at the top of said vessel (10), and the system furthermore includes a fluid line (19) communicating with said vent opening (18) in said vessel (10) and having shut-off means (20) arranged therein operative to prevent the flow of liquid from said vessel (10) through said fluid line (19).

11. The system of claim 10, wherein said flow regulating means (13a) comprises a suction pump (13a) arranged in said third fluid conducting means (8) and wherein said fluid line (19) communicates with said third fluid conducting means (8) upstream of said suction pump (13a).

12. The system of claim 10, wherein said first fluid conducting means (1) includes a suction pump (5) arranged therein for withdrawing water from said source (2) of water, and wherein said fluid line (19b) communicates with said first fluid conducting means (1) upstream of said suction pump (5).

13. The system of claim 1, wherein said vessel comprises a first vessel (10) containing a first concentrate in powder form, and wherein said system further includes a source (25;25e;50; $10g_2$) or a second concentrate fluid and means (24;24e;51-52;$8g_2$) for introducing said second concentrate fluid into said first fluid conducting means (1) to be mixed with said first concentrate fluid and water being conducted through said first fluid conducting means (1).

14. The system of claim 13, wherein said source of second concentrate fluid comprises a source (25;25e;50) of a second concentrate in liquid form.

15. The system of claim 13, wherein said mixing point comprises a first mixing point (7), and wherein said means for introducing comprises fourth fluid conducting means (24;24e;$8g_2$) communicating with said source (25;25e;$10g_2$) of second concentrate and with a second mixing point (23;23e;23g) in said first fluid conducting means (1) intermediate said first and second ends and spaced from said first mixing point (7) for conducting said second concentrate fluid into said first fluid conducting means (1).

16. The system of claim 13, wherein said source of second concentrate fluid comprises a second vessel ($10g_2$) containing a second concentrate in powder form, and fourth fluid conducting means ($8g_2$)

communicating with said source (2) of water and an inlet of said second vessel ($10g_2$) for introducing water from said source (2) of water into said second vessel ($10g_2$) to produce said second concentrate fluid.

17. The system of claim 1, wherein said vessel (10) contains a concentrate in powder form having a particle size which is greater than 100 microns.

18. The system of claim 17, wherein said concentrate (11) in powder form comprises a bicarbonate material having a particle size between 130 and 500 microns.

19. The system of claim 1, further including water determining means (57-59) for determining, if water is present in said vessel (10) and preferably also alarm means for generating an alarm signal, if water is present in said vessel prior to start-up of said system, said alarm means being responsive to said water determining means.

20. The system of claim 1, wherein said vessel (10) comprises a self-contained cartridge containing a quantity of concentrate in powder form therein which is suitable for one treatment procedure, and wherein said cartridge comprises a closed vessel (10f) having penetratable membranes (62,64) at said inlet and said outlet thereof, and wherein said second and third fluid conducting means (8,8) communicate with said inlet and said outlet, respectively, of said closed vessel through said penetratable membranes.

21. The system of claim 20, further including connecting devices (46,47) for connecting said second and third fluid conducting means (8,8) to said cartridge vessel (10f), said connecting devices each having a first end for penetrating one of said penetratable membranes (62,64) and a second end to which one of said fluid conducting means (8,8) is connected.

22. The system of claim 21, further including a holder (43) for holding said vessel (10f) and wherein said connecting devices (46,47) are mounted to said holder.

23. The system of claim 20, wherein the contents of said cartridge are internally sterilized, preferably by means of radiation, such as gamma radiation.

24. The system of claim 20, wherein said cartridge contains a sodium bicarbonate material in powder form, the quantity of said bicarbonate material in said cartridge being of the order of 400 to 900 grams, preferably approximately 600 grams.

25. The system of claim 20, wherein said cartridge contains a sodium chloride material in powder form, the quantity of material contained in said cartridge being of the order of 1000 to 3000 grams.

26. The system of claim 25, wherein the quantity of material contained in said cartridge is of the order of 1300 to 2700 grams, preferably approximately 1400 grams.

27. The system of claim 1, wherein said vessel comprises a first vessel ($10g_1$) containing a first concentrate in powder form; and wherein said system further includes a second vessel ($10g_2$) containing a second concentrate in powder form, a source (50) of liquid concentrate, fourth fluid conducting means ($8g_2$) communicating with said source (2) of water for introducing water into said second vessel ($10g_2$) to produce a second concentrate fluid containing dissolved second powder concentrate therein and for conducting said second concentrate fluid from said second vessel ($10g_2$) into said first fluid conducting means (1) intermediate said first and second ends to be mixed with fluid being conducted through said first fluid conducting means (1), and fifth fluid conducting means (51,52) communicating with said source (50) of liquid concentrate for withdrawing liquid concentrate from said source (50) of liquid concentrate and introducing said liquid concentrate into said first fluid conducing means (1) intermediate said first and second ends to be mixed with fluid being conducted through said first fluid conducting means (1), whereby said prepared solution is comprised of said first concentrate fluid, said second concentrate fluid and said liquid concentrate mixed with water withdrawn from said source (2) of water through said first fluid conducting means (1).

28. The system of claim 27, wherein said first vessel ($10g_1$) contains a sodium bicarbonate material in powder form, and said second vessel ($10g_2$) contains a salt material in powder form and wherein said liquid concentrate contains substances selected from the group consisting of an acid, calcium, potassium, magnesium, and glucose.

29. The system of claim 1, wherein said first fluid conducting means (1) includes primary flow regulating means (5) for regulating the flow of fluid through said first fluid conducting means (1), said primary flow regulating means (5) being operative to provide a flow rate of up to at least 500 ml./min. through said first fluid conducting means downstream of said mixing point (7).

30. The system of claim 29, wherein said flow regulating means (13) in said third fluid conducting means (8) is operative to provide a flow rate of up to at least 30 ml./min. of concentrate fluid through said third fluid conducting means.

31. The system of claim 30, wherein said primary flow regulating means (5) is operative to provide a flow rate of up to approximately 1000 ml./min. through said first fluid conducting means (1) downstream of said mixing point (7) and said flow regulating means (13) in said third fluid conducting means (8) is operative to provide a flow rate of up to approximately 40 ml./min. through said third fluid conducting means (8).

32. The system of claim 1, further including means for priming said system, said means for priming including valve means (32) in said third fluid conducting means (8e) intermediate said vessel (10) and said flow regulating means (13e) and a priming fluid line (66) connected to said valve means (32) and to said first fluid conducting means (1) intermediate said source (2) of water and said mixing point (7), said valve means (32) being operative to open said priming line (66) to communicate with said third fluid conducting means (8e) for priming of said system and operative to close communication between said priming line (66) and said third fluid conducting means (8e) after said system has been primed.

33. The system of claim 1, further including means for disinfection of said system, said means for disinfection including a source (39) of disinfecting solution and disinfecting fluid lines (40,42) for interconnecting said first, second and third fluid conducting means (1,8,8) in a manner to conduct disinfecting solution from said source (39) of disinfecting solution through said fluid conducting means (1,8,8), said measuring means (14) and said flow regulating means (13).

34. The system of claim 15, further including first and second measuring means (14,26) in said first fluid conducting means (1), said first measuring means (14) being downstream of said first mixing point (7) and operative to measure the composition of fluid in said first fluid conducting means (1) downstream of said first mixing point (7) and said second measuring means (26) being downstream of said second mixing point (23) and operative to measure the composition of fluid in said first fluid conducting means (1) downstream of said second mixing point (23).

35. The system of claim 34, further including first flow regulating means (13) responsive to said first measuring means (14) for controlling the flow of said first concentrate fluid through said third fluid conducting means (8), and second flow regulating means (27) responsive to said second measuring means (26) for controlling the flow of said second concentrate fluid through said fourth fluid conducting means (24).

36. The system of claim 35, wherein said first and second measuring means each comprise a conductivity measuring device.

37. The system of claim 35, further including a throttling device (3), a suction pump (5) and a deareating device (6) arranged in said first fluid conducting means (1), all arranged in said first fluid conducting means downstream of said source (2) of water and upstream of both of said first and second mixing points (7,23).

38. The system of claim 16, including a concentrate fluid circuit (8,8), said concentrate fluid circuit (8,8) including first connection means (46,47) at a first location in said concentrate fluid circuit for connecting said first vessel ($10g_1$) to said concentrate fluid circuit so as to introduce fluid containing water from

said source of water (2) into said first vessel to dissolve said first concentrate and to withdraw fluid containing said dissolved first concentrate from said first vessel, and second connection means (46,47) at a second location in said concentrate fluid circuit for connecting said second vessel ($10g_2$) to said concentrate fluid circuit so as to introduce fluid containing water from said source of water (2) into said second vessel to dissolve said second concentrate and to withdraw fluid containing said dissolved second concentrate from said second vessel, said first and second connection means being different from one another so that said first vessel is only connectable to said concentrate fluid circuit at said first location by said first connection means and said second vessel is only connectable to said concentrate fluid circuit at said second location by said second connection means.

39. The system of claim 38, wherein said first vessel ($10g_1$) has a first configuration and said second vessel ($10g_2$) has a second different configuration; and wherein said first connection means comprises a first holder (43) configured to hold a vessel having said first configuration and said second connection means comprises a second holder (43) configured to hold a vessel having said second configuration.

40. A cartridge suitable for a hemodialysis procedure, a hemofiltration procedure or a hemodiafiltration procedure with the help of a system according to anyone of the preceding claims, characterized in that it contains a quantitity of powder concentrate suitable for one treatment, arranged between a water inlet and a concentrate outlet and consisting of only one single substance.

41. A cartridge in accordance with claim 40, intended for dialysis with the use of at least one concentrate in powder form, characterized in that it contains a quantitity of the order of 400 - 900 g sodium bicarbonate, preferably approximately 600 g.

42. A cartridge in accordance with claim 40, intended for dialysis together with a cartridge according to claim 41, characterized in that it contains a quantitity of the order of 1000 - 3000 g sodium chloride, appropriately of the order of 1300 - 2700 g and preferably approximately 1400 g.

43. A cartridge in accordance with claim 40, characterized in that it is totally closed and provided with penetratable membranes at its inlet and outlet.

44. A cartridge in accordance with any of the claims 40 - 43, characterized in that it is totally closed and internally sterile.

45. A cartridge in accordance with claim 44, characterized in that it is radiation sterilized, preferably gamma radiation sterilized.

46. A cartridge in accordance with claim 40, characterized in that it has the form of a self-contained cartridge.

47. A cartridge in accordance with claim 40, characterized in that it has the form of a closed cylindrical container.

48. A method of making a self-contained cartridge, according to claim 40 for use in a system according to any of the claims 1-39 for preparing a fluid for a medical procedure, characterized in that said method comprises the steps of:

a) providing a vessel having an inlet for connection to a source of water and an outlet for delivering water flowing through the vessel to a mixing point, and

b) filling said vessel between said inlet and outlet with a charge of concentrate in powder form consisting of only one substance suitable for at least one treatment procedure so that said concentrate becomes dissolved in water flowing through the vessel between said inlet and said outlet, the amount of concentrate in said charge being sufficient for at least one treatment procedure.

49. A method of making a self-contained cartridge as claimed in claim 48, wherein said vessel comprises fluid penetratable membranes at the inlet and outlet thereof for retaining said powder in the vessel.

50. A method of making a self-contained cartridge as claimed in claim 48, wherein said vessel is in the form of a closed cylindrical container.

51. A method of making a self-contained cartridge as claimed in claim 48, further comprising the step of the internally sterilizing the contents of said vessel.

52. A method of making a self-contained cartridge as claimed in claim 48, further comprising the step of sterilizing the contents of said cartridge by means of radiation.

53. A method of making a self-contained cartridge as claimed in claim 48, further comprising the step sterilizing the contents of said cartridge by exposing them to gamma radiation.

54. A method of making a self-contained cartridge as claimed in any of claims 48 - 53, wherein said concentrate contains a sodium bicarbonate material in powder form, the quantity of said sodium bicarbonate material in said charge being of the order of 400 to 900 g, preferably approximately 600 grams.

55. A method of making a self-contained cartridge as claimed in anyone of claims 48 - 53, wherein said charge contains sodium chloride material in powder form, the quantity of salt material contained in said cartridge being of the order of 1000 to 3000 grams, appropriately of the order of 1300 to 2700 grams, preferably approximately 1400 grams.

56. A method of making a self-contained cartridge as claimed in any of claims 48 - 53, wherein the amount of concentrate in said charge is suitable for one treatment procedure.

57. A method of making a self-contained cartridge as claimed in any of claims 48 - 53, wherein said concentrate suitable for use in a hemodialysis procedure, a hemofiltration procedure or a hemodiafiltration procedure.

58. The use of a charge of concentrate in powder form suitable for at least one medical treatment procedure namely a hemodialysis procedure, a hemofiltration procedure or a hemodiafiltration procedure and consisting of only one substance to fill a cartridge according to claim 40 for use in a system as claimed in anyone of claims 1 - 39, the vessel having an inlet for connection to a source of water and an outlet for delivering water flowing through the vessel to a mixing point, and said charge of concentrate being placed between said inlet and outlet of said vessel so that in operation the concentrate becomes dissolved in water flowing through the vessel.

59. The use as claimed in claim 58, wherein said vessel comprises fluid penetratable membranes at the inlet and outlet thereof for retaining said powder in the vessel.

60. The use as claimed in claim 58, wherein said vessel is in the form of a closed cylindrical container.

61. The use as claimed in claim 58, wherein the contents of said vessel are internally sterilized.

62. The use as claimed in claim 58, wherein the contents of said cartridge are sterilized by means of radiation, preferably by gamma radiation.

63. The use as claimed in claim 58, wherein said charge is a sodium bicarbonate material in powder form, the quantity of said sodium bicarbonate material in said charge being of the order of 400 to 900 grams, preferably approximately 600 grams.

64. The use as claimed in claim 58, wherein said charge contains sodium chloride material in powder form, the quantity of salt material contained in said cartridge being of the order of 1000 to 3000 grams, appropriately of the order of 1300 to 2700 grams and preferably approximately 1400 grams.

65. The use as claimed in claim 58, wherein the amount of concentrate in said charge is suitable for one treatment procedure.

Revendications

1. Système de préparation d'un fluide pour une procédure médicale, par mélange d'au moins un

concentré sous forme de poudre avec de l'eau, ledit système étant caractérisé par :

un récipient (10) pour contenir un concentré (11) sous forme de poudre consistant essentiellement en une seule substance ;

une première conduite de fluide (1) ayant une première extrémité, pour communication avec une source (2) d'eau afin d'introduire de l'eau dans ladite première conduite de fluide, et une deuxième extrémité pour délivrer une solution préparée ;

une deuxième conduite de fluide (8) ayant une première extrémité, pour communication avec une source d'eau (2), et une deuxième extrémité qui communique avec une entrée dudit récipient (10) pour introduire de l'eau dans ledit récipient (10) afin de produire un fluide concentré contenant la poudre de concentré dissoute dans l'eau ;

une troisième conduite de fluide (8) communiquant avec une sortie dudit récipient (10) et avec un point de mélange (7) situé dans ladite première conduite de fluide (1) entre lesdites première et deuxième extrémités, pour conduire ledit fluide concentré dudit récipient (10) à ladite première conduite de fluide (1) afin de le mélanger avec le fluide de ladite première conduite de fluide (1), de manière à produire une solution préparée dans ladite première conduite de fluide (1) pour fourniture à ladite deuxième extrémité de ladite première conduite de fluide (1) ;

des moyens de mesure (14) placés dans ladite première conduite de fluide (1) en aval dudit point de mélange (7), pour mesurer la composition de la solution préparée obtenue par mélange dudit fluide concentré et de l'eau dans ladite première conduite de fluide (1) ; et

des moyens de régulation de débit (13) placés dans ladite troisième conduite de fluide (8) et qui répondent auxdits moyens de mesure (14) pour régler le débit dudit fluide concentré venant dudit récipient (10).

2. Système suivant la revendication 1, comprenant en outre une source commune (2) d'eau pour les dites première et deuxième conduites de fluide (1,8), la dite première extrémité de ladite première conduite de fluide (1) et de ladite deuxième conduite de fluide (8) communiquant chacune avec ladite source commune (2) d'eau.

3. Système suivant la revendication 2, dans lequel ladite source commune (2) d'eau comprend un réservoir (2) pour contenir de l'eau.

4. Système suivant la revendication 1, dans lequel lesdits moyens de mesure (14) comprennent un dispositif de mesure de conductivité (14).

5. Système suivant la revendication 1, dans lequel lesdits moyens de régulation de débit (13) comprennent un dispositif à étranglement (13).

6. Système suivant la revendication 3, comprenant en outre une pompe d'aspiration (5) placée dans ladite première conduite de fluide (1) en aval du dit point de mélange (7) pour faire circuler l'eau dudit réservoir (2) dans ladite première conduite de fluide (1) et pour faire circuler l'eau dudit réservoir (2) dans lesdites deuxième et troisième conduites de fluide (8,8).

7. Système suivant la revendication 6, comprenant en outre un dispositif à étranglement (3) placé dans ladite première conduite de fluide (1) entre ledit réservoir (2) et ledit point de mélange (7), et comprenant en outre un dispositif de désaération (6) placé dans ladite première conduite de fluide (1) en aval de ladite pompe d'aspiration (5).

8. Système suivant la revendication 1, dans lequel lesdits moyens de régulation de débit (13a) comprennent une pompe d'aspiration (13a).

9. Système suivant la revendication 1, dans lequel ladite entrée dudit récipient (10) est située à sa partie supérieure et ladite sortie dudit récipient (10) est située à sa partie inférieure de sorte que l'eau est conduite à travers ledit récipient (10) du haut vers le bas de celui-ci, afin de maintenir un niveau de concentration relativement constant du concentré en poudre dissous dans ladite troisième conduite de fluide (8).

10. Système suivant la revendication 1, dans lequel ledit récipient (10) comprend un orifice d'évent (18) prévu au sommet dudit récipient (10), et le système comprend en outre un tuyau de fluide (19)

communiquant avec ledit orifice d'évent (18) dudit récipient (10) et comportant des moyens de fermeture (20) qui servent à empêcher l'écoulement de liquide à partir dudit récipient (10) dans ledit tuyau de fluide (19).

11. Système suivant la revendication 10, dans lequel lesdits moyens de régulation de débit (13a) comprennent une pompe d'aspiration (13a) placée dans la dite troisième conduite de fluide (8), et dans lequel le dit tuyau de fluide (19) communique avec ladite troisième conduite de fluide (8) en amont de ladite pompe d'aspiration (13a).

12. Système suivant la revendication 10, dans lequel ladite première conduite de fluide (1) comprend une pompe d'aspiration (5), placée dans cette conduite pour prélever de l'eau de ladite source (2) d'eau, et dans lequel ledit tuyau de fluide (19b) communique avec ladite première conduite de fluide (1) en amont de ladite pompe d'aspiration (5).

13. Système suivant la revendication 1, dans lequel ledit récipient comprend un premier récipient (10) contenant un premier concentré sous forme de poudre, et dans lequel ledit système comprend en outre une source (25;25e;50; $10g_2$) d'un deuxième fluide concentré et des moyens (24;24e;51-52;$8g_2$) pour introduire ledit deuxième fluide concentré dans ladite première conduite de fluide (1) afin de le mélanger avec le dit premier fluide concentré et l'eau véhiculés dans la dite première conduite de fluide (1).

14. Système suivant la revendication 13, dans lequel ladite source de deuxième fluide concentré comprend une source (25;25e;50) d'un deuxième concentré sous forme liquide.

15. Système suivant la revendication 13, dans lequel ledit point de mélange comprend un premier point de mélange (7), et dans lequel lesdits moyens d' introduction comprennent une quatrième conduite de fluide (24;24e;$8g_2$) communiquant avec ladite source (25;25e;$20g_2$) de deuxième concentré et avec un deuxième point de mélange (23;23e;23g) dans ladite première conduite de fluide (1) entre lesdites première et deuxième extrémités et espacé dudit premier point de mélange (7), pour introduire ledit deuxième fluide concentré dans la dite première conduite de fluide (1).

16. Système suivant la revendication 13, dans lequel ladite source de deuxième fluide concentré comprend un deuxième récipient ($10g_2$) contenant un deuxième concentré sous forme de poudre, et une quatrième conduite de fluide ($8g_2$) communiquant avec ladite source (2) d'eau et une entrée dudit deuxième récipient ($10g_2$) pour introduire l'eau de ladite source (2) d'eau dans ledit deuxième récipient ($10g_2$) afin de produire ledit deuxième fluide concentré.

17. Système suivant la revendication 1, dans lequel ledit récipient (10) contient un concentré sous forme de poudre ayant une granulométrie supérieure à 100 µm.

18. Système suivant la revendication 17, dans lequel ledit concentré (11) sous forme de poudre comprend une matière de type bicarbonate ayant une granulométrie comprise entre 130 et 500 µm.

19. Système suivant la revendication 1, comprenant en outre des moyens de détermination d'eau (57-59) pour déterminer si de l'eau est présente dans le dit récipient (10), et de préférence également des moyens d'alarme pour fournir un signal d'alarme si de l'eau est présente dans ledit récipient avant le démarrage dudit système, lesdits moyens d'alarme répondant auxdits moyens de détermination d'eau.

20. Système suivant la revendication 1, dans lequel ledit récipient (10) comprend une cartouche autonome contenant une certaine quantité de concentré sous forme de poudre, qui convient pour une procédure de traitement, et dans lequel ladite cartouche comprend un récipient fermé (10f) pourvu de membranes pénétrables (62,64) à ses entrée et sortie, et dans lequel lesdites deuxième et troisième conduites de fluide (8,8) communiquent avec ladite entrée et ladite sortie, respectivement, dudit récipient fermé, à travers lesdites membranes pénétrables.

21. Système suivant la revendication 20, comprenant en outre des dispositifs de connexion (46,47) pour connecter lesdites deuxième et troisième conduites de fluide (8,8) audit récipient de cartouche (10f), les dits dispositifs de connexion avant chacun une première extrémité, pour traverser une desdites

membranes pénétrables (62,64), et une deuxième extrémité à laquelle est raccordée une desdites conduites de fluide (8,8).

22. Système suivant la revendication 21, comprenant en outre un support (43) pour tenir ledit récipient (10f) et dans lequel lesdits dispositifs de connexion (46,47) sont montés sur ledit support.

23. Système suivant la revendication 20, dans lequel le contenu de ladite cartouche est stérilisé à l'intérieur, de préférence au moyen d'un rayonnement, tel qu'un rayonnement gamma.

24. Système suivant la revendication 20, dans lequel ladite cartouche contient une matière de type bicarbonate de sodium en poudre, la quantité de ladite matière de type bicarbonate dans ladite cartouche étant de l'ordre de 400 à 900 grammes, et de préférence de 600 grammes environ.

25. Système suivant la revendication 20, dans lequel ladite cartouche contient une matière de type chlorure de sodium en poudre, la quantité de matière contenue dans ladite cartouche étant de l'ordre de 1000 à 3000 grammes.

26. Système suivant la revendication 25, dans lequel la quantité de matière contenue dans ladite cartouche est de l'ordre de 1300 à 2700 grammes, et de préférence de 1400 grammes environ.

27. Système suivant la revendication 1, dans lequel ledit récipient comprend un premier récipient ($10g_1$) contenant un premier concentré en poudre, et dans lequel ledit système comprend en outre un deuxième récipient ($10g_2$) contenant un deuxième concentré en poudre,une source (50) de concentré liquide, une quatrième conduite de fluide ($8g_2$) communiquant avec ladite source (2) d'eau pour introduire de l'eau dans le dit deuxième récipient ($10g_2$) afin de produire un deuxième fluide concentré contenant le deuxième concentré en poudre dissous et pour conduire ledit deuxième fluide concentré dudit deuxième récipient ($10g_2$) à ladite première conduite de fluide (1) entre lesdites première et deuxième extrémités afin de le mélanger avec le fluide véhiculé dans ladite première conduite de fluide (1), et une cinquième conduite de fluide (51,52), communiquant avec ladite source (50) de concentré liquide pour extraire le concentré liquide de ladite source (50) de concentré liquide etintroduire ledit concentré liquide dans ladite première conduite de fluide (1) entre les dites première et deuxième extrémités afin de le mélanger avec le fluide véhiculé dans ladite première conduite de fluide (1), de sorte que ladite solution préparée est composée dudit premier fluide concentré, dudit deuxième fluide concentré et dudit concentré liquide mélangé à l'eau extraite de ladite source (2) d'eau par ladite première conduite de fluide (1).

28. Système suivant la revendication 27, dans lequel ledit premier récipient ($10g_1$) contient une matière de type bicarbonate de sodium en poudre et ledit deuxième récipient ($10g_2$) contient une matière de type sel en poudre, et dans lequel ledit concentré liquide contient des substances choisies dans le groupe comprenant un acide, le calcium, le potassium, le magnésium et le glucose.

29. Système suivant la revendication 1, dans lequel ladite première conduite de fluide (1) comprend des moyens principaux de régulation de débit (5) pour régler le débit de fluide dans ladite première conduite de fluide (1), lesdits moyens principaux de régulation de débit (5) agissant pour fournir un débit juqu'à au moins 500 ml/min par l'intermédiaire de ladite première conduite de fluide en aval dudit point de mélange (7).

30. Système suivant la revendication 29, dans lequel lesdits moyens de régulation de débit (13) dans ladite troisième conduite de fluide (8) agissent pour fournir un débit pouvant atteindre au moins 30 ml/min de fluide concentré dans ladite troisième conduite de fluide.

31. Système suivant la revendication 30, dans lequel lesdits moyens principaux de régulation de débit (5) agissent pour fournir un débit jusqu'à 1000 ml/min environ dans ladite première conduite de fluide (1) en aval dudit point de mélange (7) et lesdits moyens de régulation de débit (13) dans ladite troisième conduite de fluide (8) agissent pour fournir un débit jusqu'à 40 ml/min environ dans ladite troisième conduite de fluide (8).

32. Système suivant la revendication 1, comprenant en outre des moyens d'amorçage dudit système,

lesdits moyens d'amorçage comprenant une vanne (32), placée dans ladite troisième conduite de fluide (8e) entre ledit récipient (10) et lesdits moyens de régulation de débit (13e), et un tuyau de fluide d'amorçage (66) connecté à ladite vanne (32) et à ladite première conduite de fluide (1) entre ladite source (2) d'eau et ledit point de mélange (7), ladite vanne (32) permettant d'ouvrir ledit tuyau d'amorçage (66) en communication avec ladite troisième conduite de fluide (8e) pour l'amorçage dudit système et permettant de fermer la communication entre ledit tuyau d'amorçage (6) et ladite troisième conduite de fluide (8e) après amorçage dudit système.

33. Système suivant la revendication 1, comprenant en outre des moyens de désinfection dudit système, lesdits moyens de désinfection comprenant une source (39) de solution de désinfection et des tuyaux de fluide de désinfection (40,42) pour interconnecter les dites première, deuxième et troisième conduites de fluide (1,8,8) de manière à diriger la solution de désinfection, à partir de ladite source (39) de solution de désinfection, à travers lesdites conduites de fluide (1,8,8), les dits moyens de mesure (14) et lesdits moyens de régulation de débit (13).

34. Système suivant la revendication 15, comprenant en outre des premiers et deuxièmes moyens de mesure (14,26) placés dans ladite première conduite de fluide (1), lesdits premiers moyens de mesure (14) étant situés en aval dudit premier point de mélange (7) et agissant pour mesurer la composition du fluide dans la dite première conduite de fluide (1) en aval dudit premier point de mélange (7), et lesdits deuxièmes moyens de mesure (26) étant situés en aval dudit deuxième point de mélange (23) et agissant pour mesurer la composition du fluide dans ladite première conduite de fluide (1) en aval dudit deuxième point de mélange (23).

35. Système suivant la revendication 34, comprenant en outre des premiers moyens de régulation de débit (13) qui répondent auxdits premiers moyens de mesure (14) pour régler le débit dedit premier fluide concentré dans ladite troisième conduite de fluide (8), et des deuxièmes moyens de régulation de débit (27) qui répondent auxdits deuxièmes moyens de mesure (26) pour régler le débit dedit deuxième fluide concentré dans ladite quatrième conduite de fluide (24).

36. Système suivant la revendication 35, dans lequel lesdits premier et deuxième moyens de mesure comprennent chacun un dispositif de mesure de conductivité.

37. Système suivant la revendication 35, comprenant en outre un dispositif à étranglement (3), une pompe d'aspiration (5) et un dispositif de désaération (6) placés dans ladite première conduite de fluide (1) et tous situés dans ladite première conduite de fluide en aval de ladite source (2) d'eau et en amont à la fois desdits premier et deuxième points de mélange (7,23).

38. Système suivant la revendication 16, comprenant un circuit de fluide concentré (8,8),ledit circuit de fluide concentré (8,8) comprenant des premiers moyens de connexion (46,47) à un premier endroit dans le dit circuit de fluide concentré pour connecter ledit premier récipient($10g_1$) audit circuit de fluide concentré de manière à introduire un fluide contenant de l'eau provenant de ladite source d'eau (2) dans ledit premier récipient afin de dissoudre ledit premier concentré et de manière à extraire un fluide contenant ledit premier concentré dissous dudit premier récipient, et des deuxièmes moyens de connexion (46,47) à un deuxième endroit dans ledit circuit de fluide concentré pour connecter ledit deuxième récipient ($10g_2$) audit circuit de fluide concentré de manière à introduire un fluide contenant de l'eau provenant de ladite source d'eau (2) dans ledit deuxième récipient afin de dissoudre ledit deuxième concentré et de manière à extraire un fluide contenant le dit deuxième concentré dissous dudit deuxième récipient, lesdits premiers et deuxièmes moyens de connexion étant mutuellement différents de sorte que ledit premier récipient peut seulement être connecté audit circuit de fluide concentré audit premier endroit par lesdits premiers moyens de connexion et ledit deuxième récipient peut seulement être connecté audit circuit de fluide concentré audit deuxième endroit par lesdits deuxièmes moyens de connexion.

39. Système suivant la revendication 38, dans lequel ledit premier récipient ($10g_1$) présente une première configuration et ledit deuxième récipient ($10g_2$) présente une deuxième configuration différente, et dans lequel lesdits premiers moyens de connexion comprennent un premier support (43) apte à tenir un récipient ayant ladite première configuration et lesdits deuxièmes moyens de connexion comprennent un deuxième support (43) apte à tenir un récipient ayant ladite deuxième configuration.

40. Cartouche destinée à être utilisée pour exécuter un traitement thérapeutique à l'aide d'un système suivant l'une quelconque des revendications précédentes, caractérisée en ce qu'elle contient une quantité de concentré enpoudre appropriée à un seul traitement, disposée entre une entrée d'eau et une sortie de concentré et consistant sensiblement en une seule substance.

41. Cartouche suivant la revendication 40, destinée à une dialyse au moyen d'au moins un concentré en poudre, caractérisée en ce qu'elle contient une quantité de l'ordre de 400 à 900 grammes de bicarbonate de sodium, et de préférence 600 grammes environ.

42. Cartouche suivant la revendication 40, destinée à une dialyse en association avec une cartouche suivant la revendication 41,caractérisée en ce qu'elle contient une quantité de l'ordre de 1000 à 3000 grammes de chlorure de sodium, avantageusement 1300 à 2700 grammes et de préférence 1400 grammes environ.

43. Cartouche suivant la revendication 40, caractérisée en ce qu'elle est totalement fermée et comporte des membranes pénétrables à son entrée et à sa sortie.

44. Cartouche suivant l'une quelconque des revendications 40 à 43, caractérisée en ce qu'elle est totalement fermée et intérieurement stérile.

45. Cartouche suivant la revendication 44, caractérisée en ce qu'elle est stérilisée par irradiation, et de préférence stérilisée par irradiation gamma.

46. Cartouche suivant la revendication 40, carctérisée en ce qu'elle a la forme d'une cartouche autonome.

47. Cartouche suivant la revendication 40, caractérisée en ce qu'elle a la forme d'un récipient cylindrique fermé.

48. Méthode de fabrication d'une cartouche autonome, suivant la revendication 40, utilisable dans un système suivant l'une quelconque des revendications 1 à 39 pour la préparation d'un fluide pour une procédure médicale, caractérisée en ce que ladite méthode comprend les opérations de :
(a) préparation d'un récipient comportant une entrée pour raccordement à une source d'eau et une sortie pour fourniture de l'eau ayant traversé le récipient à un point de mélange, et
(b) remplissage dudit récipient, entre ladite entrée et ladite sortie, avec une charge de concentré en poudre, consistant en une seule substance appropriée à au moins une procédure de traitement, de sorte que ledit concentré se dissout dans l'eau qui circule dans le récipient entre ladite entrée et ladite sortie, la quantité de concentré dans ladite charge étant suffisante pour au moins une procédure de traitement.

49. Méthode de fabrication d'une cartouche autonome suivant la revendication 48, dans laquelle ledit récipient comprend des membranes pénétrables à son entrée et à sa sortie, pour retenir ladite poudre dans le récipient.

50. Méthode de fabrication d'une cartouche autonome suivant la revendication 48, dans laquelle ledit récipient est sous la forme d'un récipient cylindrique fermé.

51. Méthode de fabrication d'une cartouche autonome suivant la revendication 48, comprenant en outre l'opération de stérilisation interne du contenu du dit récipient.

52. Méthode de fabrication d'une cartouche autonome suivant la revendication 48, comprenant en outre l'opération de stérilisation du contenu de ladite cartouche par irradiation.

53. Méthode de fabrication d'une cartouche autonome suivant la revendication 48, comprenant en outre l'opération de stérilisation du contenu de ladite cartouche par exposition de ce contenu à un rayonnement gamma.

54. Méthode de fabrication d'une cartouche autonome suivant l'une quelconque des revendications 48 à 53, dans laquelle ledit concentré contient une matière de type bicarbonate de sodium en poudre, la

quantité de ladite matière de type bicarbonate de sodium dans ladite charge étant de l'ordre de 400 à 900 grammes et de préférence de 600 grammes environ.

55. Méthode de fabrication d'une cartouche autonome suivant l'une quelconque des revendications 48 à 53, dans laquelle ladite charge contient une matière de type chlorure de sodium en poudre, la quantité de matière de type sel contenue dans ladite cartouche étant de l'ordre de 1000 à 3000 grammes, avantageusement de l'ordre de 1300 à 2700 grammes et de préférence de 1400 grammes environ.

56. Méthode de fabrication d'une cartouche autonome suivant l'une quelconque des revendications 48 à 53, dans laquelle la quantité de concentrat dans ladite charge convient pour une procédure de traitement.

57. Méthode de fabrication d'une cartouche autonome suivant l'une quelconque des revendications 48 à 53, dans laquelle ledit concentré convient pour l'utilisation dans une procédure d'hémodialyse, une procédure d'hémofiltration ou une procédure d'hémodiafiltration.

58. Utilisation d'une charge de concentré en poudre convenant pour au moins une procédure de traitement médical, notamment une procédure d'hémodialyse, une procédure d'hémofiltration ou une procédure d'hémodiafiltration, et consistant en une seule substance pour remplir une cartouche suivant la revendication 40, utilisable dans un système suivant l'une quelconque des revendications 1 à 39, le récipient comportant une entrée pour raccordement à une source d'eau et une sortie pour distribution de l'eau traversant le récipient à un point de mélange, et ladite charge de concentré étant placée entre ladite entrée et ladite sortie dudit récipient de sorte que, en fonctionnement, le concentré se dissout dans l'eau qui circule dans le récipient.

59. Utilisation suivant la revendication 58, dans laquelle ledit récipient comprend des membranes pénétrables à son entrée et à sa sortie, pour retenir la dite poudre dans le récipient.

60. Utilisation suivant la revendication 58, dans laquelle ledit récipient est sous la forme d'un récipient cylindrique fermé.

61. Utilisation suivant la revendication 58, dans laquelle le contenu dudit récipient est stérilisé intérieurement.

62. Utilisation suivant la revendication 59, dans laquelle le contenu de ladite cartouche est stérilisé au moyen d'un rayonnement, de préférence un rayonnement gamma.

63. Utilisation suivant la revendication 59, dans laquelle ladite charge est une matière de type bicarbonate de sodium en poudre, la quantité dedite matière de type bicarbonate de sodium dans ladite charge étant de l'ordre de 400 à 900 grammes et de préférence de 600 grammes environ.

64. Utilisation suivant la revendication 58, dans laquelle ladite charge contient une matière de type chlorure de sodium en poudre, la quantité de sel contenue dans ladite cartouche étant de l'ordre de 1000 à 3000 grammes, avantageusement de l'ordre de 1300 à 2700 grammes et de préférence de 1400 grammes environ.

65. Utilisation suivant la revendication 58, dans laquelle la quantité de concentré dans ladite charge convient pour une seule procédure de traitement.

Patentansprüche

1. System zur Herstellung eines Fließmittels für ein medizinisches Verfahren durch Vermischen wenigstens eines Konzentrates in Pulverform mit Wasser, gekennzeichnet durch:
einen Behälter (10), der ein Konzentrat (11) in Pulverform enthält, das im wesentlichen aus nur einer einzigen Substanz besteht;
eine erste Fließmittelleitungseinrichtung (1) mit einem ersten Ende für eine Verbindung mit einer Wasserquelle (2), um Wasser in die erste Fließmittelleitungseinrichtung abzuziehen, und mit einem zweiten Ende zur Abgabe einer bereiteten Lösung;

eine zweite Fließmittelleitungseinrichtung (8) mit einem ersten Ende zur Verbindung mit einer Wasserquelle (2) und einem zweiten Ende, das mit einem Einlaß des Behälters (10) zur Einführung von Wasser in den Behälter verbunden ist, um ein Konzentratfließmittel zu erzeugen, das gelöstes Pulverkonzentrat in Wasser enthält;
eine dritte Fließmittelleitungseinrichtung (8), die in Verbindung mit einem Auslaß des Behälters (10) und mit einem Vermischungspunkt (7) in dererstenFließmittelleitungseinrichtung (1) zwischen dem ersten und zweiten Ende zur Führung des Konzentratfließmittels von dem Behälter (10) in die erste Fließmittelleitungseinrichtung (1) verbunden ist, um mit Fließmittel vermischt zu werden, das durch die erste Fließmittelleitungseinrichtung (1) geführt wird, um so eine bereitete Lösung in der ersten Fließmittelleitungseinrichtung (1) zur Abgabe an das zweite Ende der ersten Fließmittelleitungseinrichtung (1) zu erzeugen;
eine Meßeinrichtung (14) in der ersten Fließmittelleitungseinrichtung (1) abstromwärts von dem Vermischungspunkt (7) zur Messung der Zusammensetzung der bereiteten Lösung, die durch Vermischen des Konzentratfließmittels und von Wasser in der ersten Fließmittelleitungseinrichtung (1) erhalten wurde;
und eine Strömungsregeleinrichtung (13) in der dritten Fließmittelleitungseinrichtung (8), die in Abhängigkeit von der Meßeinrichtung (14) zur Steuerung des Stromes des Konzentratfließmittels aus dem Behälter (10) arbeitet.

2. System nach Anspruch 1, zusätzlich mit einer gemeinsamen Wasserquelle (2) für die erste und zweite Fließmittelleitungseinrichtung (1, 8), wobei die ersten Enden der ersten Fließmittelleitungseinrichtung (1) und der zweiten Fließmittelleitungseinrichtung (8) jeweils in Verbindung mit dieser gemeinsamen Wasserquelle (2) stehen.

3. System nach Anspruch 2, bei dem die gemeinsame Wasserquelle (2) einen Vorratsbehälter (2) für Wasser umfaßt.

4. System nach Anspruch 1, bei dem die Meßeinrichtung (14) eine Leitfähigkeitsmeßeinrichtung (14) umfaßt.

5. System nach Anspruch 1, bei dem die Strömungsregeleinrichtung (13) eine Drosseleinrichtung (13) umfaßt.

6. System nach Anspruch 3, weiterhin mit einer Saugpumpe (5), die in der ersten Fließmittelleitungseinrichtung (1) abstromwärts von dem Vermischungspunkt (7) zur Führung von Wasservon dem Behälter (2) durch die erste Fließmittelleitungseinrichtung (1) und zur Führung von Wasser von dem Behälter (2) durch die zweite und dritte Fließmittelleitungseinrichtung (8, 8) angeordnet ist.

7. System nach Anspruch 6, weiterhin mit einer Drosseleinrichtung (3), die in der ersten Fließmittelleitungseinrichtung (1) zwischendem Behälter (2) und dem Vermischungspunkt (7) angeordnet ist, und weiterhin mit einer Entlüftungseinrichtung (6), die in der ersten Fließmittelleitungseinrichtung (1) abstromwärts von der Saugpumpe (5) angeordnet ist.

8. System nach Anspruch 1, bei dem die Strömungsregeleinrichtung (13a) eine Saugpumpe (13a) umfaßt.

9. System nach Anspruch 1, beidem der Einlaß des Behälters (10) an dessen oberem Ende liegt und der Auslaß des Behälters (10) an dessen Boden liegt, so daß Wasser durch den Kessel (10) von dessen oberem Ende zu dessen Bodengeführtwird, um dabei eine relativ konstante Konzentration an gelöstem Pulverkonzentrat in der dritten Fließmittelleitungseinrichtung (8) aufrechtzuerhalten.

10. System nach Anspruch 1, bei dem der Behälter (10) eine Lüftungsöffnung (18) enthält, die darin an dem oberen Ende des Behälters (10) angeordnet ist, und das System außerdem eine Fließmittelleitung (19) enthält, die mit der Lüftungsöffnung (18) des Behälters (10) verbunden ist und eine Absperreinrichtung (20) hat, die darin derart arbeitend angeordnet ist, daß sie den Flüssigkeitsfluß von dem Behälter (10) durch die Fließmittelleitung (19) verhindert.

11. System nach Anspruch 10, bei dem die Strömungsregeleinrichtung (13a) eine Saugpumpe (13a) umfaßt, die in der dritten Fließmittelleitungseinrichtung (8) angeordnet ist, und bei der die Fließmittellei-

tung (19) in Verbindung mit der dritten Fließmittelleitungseinrichtung (8) abstromwärts von der Saugpumpe (13a) steht.

12. System nach Anspruch 10, bei dem die erste Fließmittelleitungseinrichtung (1) eine Saugpumpe (5) enthält, die
darin angeordnet ist, um Wasser von der Wasserquelle (2) abzuziehen, und bei dem die Fließmittelleitung (19b) in Verbindung mit der ersten Fließmittelleitungseinrichtung (1) aufstromwärts von der Saugpumpe (5) steht.

13. System nach Anspruch 1, bei dem der Behältereinen ersten Behälter (10), derein erstes Konzentrat in Pulverform enthält, umfaßt und bei dem das System weiterhin eine Quelle (25; 25e; 50; $10g_2$) für ein zweites Konzentrat-fließmittel sowie eine Einrichtung (24; 24e; 51 - 52; $8g_2$) zur Einführung des zweiten Konzentratfließmittels in die erste Fließmittelleitungseinrichtung (1) enthält, um mit dem ersten Konzentratfließmittel und Wasser vermischt zu werden und um Wasserdurch die erste Fließmittelleitungseinrichtung (1) zu führen.

14. System nach Anspruch 13, bei dem die Quelle für das zweite Konzentratfließmittel eine Quelle (25; 25e; 50) für ein zweites Konzentrat in flüssiger Form umfaßt.

15. System nach Anspruch 13, bei dem der Vermischungspunkteinen ersten Vermischungspunkt (7) umfaßt und bei dem die Einführungseinrichtung eine vierte Fließmittelleitungseinrichtung (24; 24e: $8g_2$) umfaßt, die mitder Quelle (25; 25e, 50) für das zweite Konzentrat und mit einem zweiten Vermischungspunkt (23; 23e; 23g) in der ersten Fließmittelleitungseinrichtung (1) zwischen dem ersten und zweiten Ende in Verbindung steht und einen Abstand von dem ersten Vermischungspunkt (7) hat, um das zweite Konzentratfließmittel in die erste Fließmittelleitungseinrichtung (1) zu führen.

16. System nach Anspruch 13, bei dem die Quelle für das zweite Konzentratfließmittel einen zweiten Behälter ($10g_2$), der ein zweites Konzentrat in Pulverform enthält, und eine vierte Fließmittelleitungseinrichtung ($8g_2$) umfaßt, die mit der Wasserquelle (2) und einem Einlaß des zweiten Behälters ($10g_2$) zur Einführung von Wasser aus der Wasserquelle (2) in den zweiten Behälter ($10g_2$) zur Erzeugung des zweiten Konzentratfließmittels in Verbindung steht.

17. System nach Anspruch 1, bei dem der Behälter (10) ein Konzentrat in Pulverform mit einer Teilchengröße enthält, welche größer als 100 Mikron ist.

18. System nach Anspruch 17, bei dem das Konzentrat (11) in Pulvertorm ein Bicarbonatmaterial mit einer Teilchengröße zwischen 130 und 500 Mikron umfaßt.

19. System nach Anspruch 1, weiterhin mit einer Wasserbestimmungseinrichtung (57 - 59) zur Bestimmung, wenn Wasser in dem Behälter (10) vorhanden ist, und vorzugsweise auch mit einer Alarmeinrichtung zur Erzeugung eines Alarmsignals, wenn Wasser in dem Behälter vor dem Anlassen des Systems vorhanden ist, wobei die Alarmeinrichtung in Abhängigkeit von der Wasserbestimmungseinrichtung arbeitet.

20. System nach Anspruch 1, bei dem der Behälter (10) eine selbständige Kartusche umfaßt, die eine Konzentratmenge in Pulverform darin enthält, welche für ein Behandlungsverfahren geeignet ist, und beidem diese Kartusche einen geschlossenen Behälter (10f) mit durchdringbaren Membranen (62, 64) an seinem Einlaß und an seinem Auslaß umfaßt und bei dem die zweite und dritte Fließmittelleitungseinrichtung (8, 8) in Verbindung mit dem Einlaß bzw. Auslaß des geschlossenen Behälters durch diese durchdringbaren Membranen steht.

21. System nach Anspruch 20, weiterhin mit Verbindungseinrichtungen (46, 47) zur Verbindung der zweiten und dritten Fließmittelleitungseinrichtung (8, 8) mit dem Kartuschenbehälter (10f), wobei die Verbindungseinrichtungen jeweils ein erstes Ende zur Durchdringung einer der durchdringbaren Membranen (62,64) und ein zweites Ende, mit welchem eine der Fließmittelleitungseinrichtungen (8, 8) verbunden ist, haben.

22. System nach Anspruch 21, weiterhin mit einem Halter (43) zum Halten des Behälters (101), wobei die

Verbindungseinrichtungen (46, 47) an diesem Halter angeordnet sind.

23. System nach Anspruch 20, bei dem der Inhalt der Kartusche im Inneren sterilisiert ist, vorzugsweise durch Strahlung, wie Gammastrahlung.

24. System nach Anspruch 20, bei dem die Kartusche ein Natriumbicarbonatmaterial in Pulverform enthält, wobei die Menge dieses Bicarbonatmaterials in der Kartusche in der Größenordnung von 400 bis 900 g, vorzugsweise etwa 600 g liegt.

25. System nach Anspruch 20, bei dem die Kartusche ein Natriumchloridmaterial in Pulverform enthält, wobei die in der Kartusche enthaltene Materialmenge in der Größenordnung von 1000 bis 3000 g liegt.

26. System nach Anspruch 25, bei dem die in der Kartusche enthaltene Materialmenge in der Größenordnung von 1300 bis 2700 g, vorzugsweise etwa 1400 g, liegt.

27. System nach Anspruch 1, bei dem der Behälter einen ersten Behälter ($10g_1$) umfaßt, welcher ein erstes Konzentrat in Pulverform enthält, und bei dem das System weiterhin einen zweiten Behälter ($10g_2$), der ein zweites Konzentrat in Pulverform enthält, eine Quelle (50) für flüssiges Konzentrat, eine vierte Fließmittelleitungseinrichtung ($8g_2$) in Verbindung mit der Wasserquelle (2) zur Einführung von Wasserin den zweiten Behälter ($10g_2$) zur Erzeugung eines zweiten Konzentratfließmittels, das darin gelöstes zweites Pulverkonzentrat enthält, und zur Führung des zweiten Konzentratfließmittels von dem zweiten Behälter ($10g_2$) in die erste Fließmittelleitungseinrichtung (1) zwischen dem ersten und zweiten Ende, um mit Fließmittel vermischt zu werden, das durch die erste Fließmittelleitungseinrichtung (1) geführt wird, und eine fünfte Fließmittelleitungseinrichtung (51, 52), die in Verbindung mit der Quelle (50) für flüssiges Konzentratzum Abziehen von flüssigem Konzentrat aus der Quelle (50) für flüssiges Konzentrat und Einführung des flüssigen Konzentrates in dieerste Fließmittelleitungseinrichtung (1) zwischen dem ersten und zweiten Ende steht, um mit Fließmittel vermischt zu werden, das durch die erste Fließmittelleitungseinrichtung (1) geführt wird, aufweist, wobei die bereitete Lösung das erste Konzentratfließmittel, das zweite Konzentratfließmittel und das flüssige Konzentrat vermischt mit Wasser umfaßt, das von der ersten Wasserquelle (2) durch die erste Fließmittelleitungseinrichtung (1) abgezogen wurde.

28. System nach Anspruch 27, bei dem der erste Behälter ($10g_1$) ein Natriumbicarbonatmaterial in Pulverform und der zweite Behälter ($10g_2$) ein Salzmaterial in Pulverform enthält und bei dem das flüssige Konzentrat eine Substanz enthält, die aus der Gruppe einer Säure, Calcium, Kalium, Magnesium und Glucose ausgewählt ist.

29. System nach Anspruch 1, bei dem die erste Fließmittelleitungseinrichtung (1) eine primäre Strömungsregulierеinrichtung (5) zur Regulierung des Fließmittelflusses durch die erste Fließmittelleitungseinrichtung (1) enthält, wobei die primäre Strömungsregulierеinrichtung (5) so arbeitet, daß sie eine Fließgeschwindigkeit von bis zu wenigstens 500 ml/min durch die erste Fließmittelleitungseinrichtung abstromwärts von dem Vermischungspunkt (7) ergibt.

30. System nach Anspruch 29, bei dem die Strömungsregulierеinrichtung (13) in der dritten Fließmittelleitungseinrichtung (8) so arbeitet, daß sie eine Fließgeschwindigkeit von bis zu wenigstens 30 ml/min an Konzentratfließmittel durch die dritte Fließmittelleitungseinrichtung ergibt.

31. System nach Anspruch 30, bei dem die primäre Strömungsregulierеinrichtung (5) so arbeitet, daß sie eine Fließgeschwindigkeit von bis zu etwa 1000 ml/min durch die erste Fließmittelleitungseinrichtung (1) abstromwärts von dem Vermischungspunkt (7) ergibt, und daß die Strömungsregulierеinrichtung (13) in der dritten Fließmittelleitungseinrichtung (8) so arbeitet, daß sie eine Fließgeschwindigkeit von bis zu etwa 40 ml/min durch die dritte Fließmittelleitungseinrichtung ergibt.

32. System nach Anspruch 1, weiterhin mit Einrichtungen zum Vorbereiten des Systems, wobei diese Einrichtungen zur Vorbereitung eine Ventileinrichtung (32) in der dritten Fließmittelleitungseinrichtung (8) zwischendem Behälter(19) und der Strömungsregulierеinrichtung (13e) und eine Vorbereitungsfließmittelleitung(66), die mit der Ventileinrichtung (32) und der ersten Fliemittelleitungseinrichtung (1) zwischen der Wasserquelle (2) und dem Vermischungspunkt (7) verbunden ist, enthalten, wobei die

Ventileinrichtung (32) derart arbeitet, daß sie die Vorbereitungsleitung (66) öffnet, damit sie mit der dritten Fließmittelleitungseinrichtung (8) in Verbindung steht, um das System vorzubereiten, und in enger Verbindung zwischen der Vorbereitungsleitung (66) und der dritten Fließmittelleitungseinrichtung (8) arbeitet, nachdem das System vorbereitet wurde.

33. System nach Anspruch 1, weiterhin mit Einrichtungen zum Desinfizieren des Systems, wobei diese Einrichtungen zum Desinfizieren eine Quelle (39) für Desinfizierlösung sowie Desinfizierfließmittelleitungen (40, 42) zur Verbindung der ersten, zweiten und dritten Fließmittelleitungseinrichtung (1, 8, 8) in solcher Weise, daß Desinfektionslösung von der Quelle (39) der Desinfektionslösung durch die Fließmittelleitungseinrichtung (1, 8, 8), die Meßeinrichtung (14) und die Strömungsreguliereinrichtung (13) geführt wird, enthalten.

34. System nach Anspruch 15, weiterhin mit ein erersten und zweiten Meßeinrichtung (14, 26) in der ersten Fließmittelleitungseinrichtung (1), wobei die erste Meßeinrichtung (14) abstromwärts von dem ersten Vermischungspunkt (7) liegt und so arbeitet, daß sie die Zusammensetzung von Fließmittel in der ersten Fließmittelleitungseinrichtung (1) abstromwärts von dem ersten Vermischungspunkt mißt, und die zweite Meßeinrichtung (26) abstromwärts von dem zweiten Vermischungspunkt (23) liegt und so arbeitet, daß sie die Fließmittelzusammensetzung in der ersten Fließmittelleitungseinrichtung (1) abstromwärts von dem zweiten Vermischungspunkt (23) mißt.

35. System nach Anspruch 34, weiterhin mit einer ersten Strömungsreguliereinrichtung (13), die in Abhängigkeit von der ersten Meßeinrichtung (14) zur Steuerung des Flusses des ersten Konzentratfließmittels durch die dritte Fließmittelleitungseinrichtung (8) arbeitet, und mit einer zweiten Strömungsreguliereinrichtung (27), die in Abhängigkeit von der zweiten Meßeinrichtung (26) zur Steuerung des Flusses des zweiten Konzentratfießmittels durch die vierte Fließmittelleitungseinrichtung (24) arbeitet.

36. System nach Anspruch 35, bei dem die erste und zweite Meßeinrichtung jeweils eine Leitfähigkeitsmeßeinrichtung umfassen.

37. System nach Anspruch 35, weiterhin mit einer Drosseleinrichtung (3), einer Saugpumpe (5) und einer Entlüftungseinrichtung (6), die in der ersten Fließmittelleitungseinrichtung (1) angeordnet ist, wobei alle in der ersten Fließmittelleitungseinrichtung abstromwärts von der Wasserquelle (2) und aufstromwärts sowohl von dem ersten als auch von dem zweiten Vermischungspunkt (7, 23) angeordnet sind.

38. System nach Anspruch 16, mit einem Konzentratfließmittelkreislauf (8, 8), wobei dieser Konzentratfließmittelkreislauf (8, 8) eine erste Verbindungseinrichtung (46, 47) an einer ersten Stelle in dem Konzentratfließmittelkreislauf zur Verbindung des ersten Behälters ($10g_1$) mit dem Konzentratfließmittelkreislauf, um so Fließmittel, das Wasser aus der Wasserquelle (2) enthält, in den ersten Behälter einzuführen und so das erste Konzentrat zu lösen, und um das gelöste erste Konzentrat enthaltende Fließmittel aus dem ersten Behälter abzuziehen, und eine zweite Verbindungseinrichtung (46, 47) an einer zweiten Stelle in dem Konzentratfließmittelkreislauf zur Verbindung des zweiten Behälters ($10g_2$) mitdem Konzentratfließmittelkreislauf, um Wasser aus der Wasserquelle (2) enthaltendes Fließmittel in den zweiten Behälter einzuführen und so das zweite Konzentrataufzulösen und um das gelöste zweite Konzentratenthaltende Fließmittel von dem zweiten Behälter abzuziehen, enthält, wobei die erste und zweite Verbindungseinrichtung voneinander verschieden sind, so daß der erste Behälter nur mit dem Konzentratfließmittelkreislauf an der ersten Stelle durch die erste Verbindungseinrichtung verbindbar ist und der zweite Behälter nur mit dem Konzentratfließmittelkreislauf an der zweiten Stelle durch die zweite Verbindungseinrichtung verbindbar ist.

39. System nach Anspruch 38, bei dem der erste Behälter ($10g_1$) eine erste Gestaltung und der zweite Behälter ($10g_2$) eine zweite hiervon verschiedene Gestaltung hat und bei dem die erste Verbindungseinrichtung einen ersten Halter (43) umfaßt, der so gestaltet ist, daß er einen Behälter mit der ersten Gestaltung hält, und die zweite Verbindungseinrichtung einen zweiten Halter (43) aufweist, der so gestaltet ist, daß er einen Behälter mit der zweiten Gestaltung hält.

40. Kartusche, geeignet für eine Hämodialyse, Hämofiltration oder Hämodiafiltration, mit Hilfe eines Systems nach einem der vorausgehenden Ansprüche, **dadurch gekennzeichnet,** daß sie eine für eine Behandlung geeignete Pulverkonzentratmenge enthält, die zwischen einem Wassereinlaß und einem

Konzentratauslaß angeordnet ist und nur aus einer einzigen Substanz besteht.

41. Kartusche nach Anspruch 40 für Dialyse unter Verwendung wenigstens eines Konzentrates in Pulverform, **dadurch gekennzeichnet,** daß sie eine Menge in der Größenordnung von 400 bis 900 g Natriumbicarbonat, vorzugsweise etwa 600 g, enthält.

42. Kartusche nach Anspruch 40 für Dialyse zusammen mit einer Kartusche nach Anspruch 41, **dadurch gekennzeichnet,** daß sie eine Menge in der Größenordnung von 1000 bis 3000 g Natriumchlorid, zweckmäßig 1300 bis 2700 g und vorzugsweise etwa 1400 g, enthält.

43. Kartusche nach Anspruch 40, **dadurch gekennzeichnet,** daß sie vollständig geschlossen und mit durchdringbaren Membranen an ihrem Einlaß und ihrem Auslaß versehen ist.

44. Kartusche nach einem der Ansprüche 40 bis 43, **dadurch gekennzeichnet,** daß sie vollständig verschlossen und im Inneren steril ist.

45. Kartusche nach Anspruch 44, **dadurch gekennzeichnet,** daß sie durch Strahlung, vorzugsweise durch Gammastrahlung, sterilisiert ist.

46. Kartusche nach Anspruch 40, **dadurch gekennzeichnet,** daß sie die Form einer selbständigen Kartusche hat.

47. Kartusche nach Anspruch 40, **dadurch gekennzeichnet,** daß sie die Form eines geschlossenen zylindrischen Behälters hat.

48. Verfahren zur Herstellung einer selbständigen Kartusche nach Anspruch 40 zur Verwendung in einem System nach einem der Ansprüche 1 bis 39 zur Herstellung eines Fließmittels für ein medizinisches Verfahren, **dadurch gekennzeichnet,** daß man:
    a) einen Behälter mit einem Einlaß für eine Verbindung mit einer Wasserquelle und einem Auslaß zur Abgabe von durch den Behälter fließendem Wasser zu einem Vermischungspunkt vorsieht und
    b) den Behälter zwischen dem Einlaß und Auslaß mit einer Konzentratbeschickung in Pulverform, die nur aus einer für wenigstens ein Behandlungsverfahren geeigneten Substanz besteht, derart füllt, daß das Konzentrat in Wasser gelöst wird, welches durch den Behälter zwischen dem Einlaß und dem Auslaß fließt, wobei die Konzentratmenge in der Beschickung von wenigtens ein Behandlungsverfahren ausreicht.

49. Verfahren zur Herstellung einer selbständigen Kartusche nach Anspruch 48, bei dem der Behälter fließmitteldurchdringbare Membranen an seinem Einlaß und seinem Auslaß umfaßt, um das Pulver in dem Behälter zurückzuhalten.

50. Verfahren zur Herstellung einer selbständigen Kartusche nach Anspruch 48, bei dem der Behälter in der Form eines geschlossenen zylindrischen Behälters vorliegt.

51. Verfahren zur Herstellung einer selbständigen Kartusche nach Anspruch 48, weiterhin mit der Stufe der Innensterilisierung des Inhalts des Behälters.

52. Verfahren zur Herstellung einer selbständigen Kartusche nach Anspruch 48, weiterhin mit der Stufe eines Sterilisierens des Inhalts der Kartsuche mit Hilfe von Strahlung.

53. Verfahren zur Herstellung einer selbständigen Kartusche nach Anspruch 48, weiterhin mit der Stufe eines Sterilisierens des Inhalts der Kartusche, indem man sie Gammastrahlung aussetzt.

54. Verfahren zur Herstellung einer selbständigen Kartusche nach einem der Ansprüche 48 bis 53, bei dem das Konzentrat ein Natriumbicarbonatmaterial in Pulverform enthält, wobei die Menge des Natriumbicarbonatmaterials in der Beschickung in der Größenordnung von 400 bis 900 g, vorzugsweise etwa 600 g, liegt.

55. Verfahren zur Herstellung einer selbständigen Kartusche nach einem der Ansprüche 48 bis 53, bei dem

die Beschickung Natriumchloridmaterial in Pulverform enthält, wobei die Menge des in der Kartusche enthaltenen Materials in der Größenordnung von 1000 bis 3000 g, zweckmäßig in der Größenordnung von 1300 bis 2700 g, vorzugsweise bei etwa 1400 g, liegt.

56. Verfahren zur Herstellung einer selbständigen Kartsuche nach einem der Ansprüche 48 bis 53, bei dem die Konzentratmenge in der Beschickung für ein Behandlungsverfahren geeignet ist.

57. Verfahren zur Herstellung einer selbständigen Kartusche nach einem der Ansprüche 48 bis 53, bei dem das Konzentrat für eine Verwendung in einem Hämodialyseverfahren, einem Hämofiltrationsverfahren oder einem Hämodiafiltrationsverfahren geeignet ist.

58. Verwendung einer Konzentratbeschickung in Pulverform, die für wenigstens ein medizinisches Behandlungsverfahren, nämlich ein Hämodialyseverfahren, ein Hämofiltrationsverfahren oder ein Hämodiafiltrationsverfahren, geeignet ist und nur aus einer Substanz besteht, zum Füllen einer Kartusche nach Anspruch 40 zur Verwendung in einem System nach einem der Ansprüche 1 bis 39, wobei der Behälter einen Einlaß für die Verbindung mit einer Wasserquelle und einen Auslaß zur Abgabe von durch den Behälter fließendem Wasser an einen Vermischungspunkt hat und die Konzentratbeschikkung zwischen dem Einlaß und Auslaß des Behälters derart angeordnet ist, daß im Betrieb das Konzentrat in durch den Behälter fließendem Wasser gelöst wird.

59. Verwendung nach Anspruch 58, bei der der Behälter fließmitteldurchdringbare Membranen an seinem Einlaß und seinem Auslaß umfaßt, um das Pulver in dem Behälter zurückzuhalten.

60. Verwendung nach Anspruch 58, bei der der Behälter in der Form eines geschlossenen zylindrischen Behälters vorliegt.

61. Verwendung nach Anspruch 58, bei der der Inhalt des Behälters im Inneren sterillsiert wird.

62. Verwendung nach Anspruch 58, bei der der Inhalt der Kartusche mit Hilfe von Strahlung, vorzugsweise mit Gammastrahlung, sterilisiert wird.

63. Verwendung nach Anspruch 58, bei der die Beschickung ein Natriumbicarbonatmaterial in Pulverform ist,wobei die Menge dieses Natriumbicarbonatmaterials in der Beschickung in der Größenordnung von 400 bis 900 g, vorzugsweise etwa 600 g, liegt.

64. Verwendung nach Anspruch 58, bei der die Beschickung Natriumchloridmaterial in Pulverform enthält, wobei die Menge an in der Kartusche enthaltenem Salzmaterial in der Größenordnung von 1000 bis 3000 g, zweckmäßig in der Größenordnung von 1300 bis 2700 g, und bevorzugt bei etwa 1400 g, liegt.

65. Verwendung nach Anspruch 58, bei der die Konzentratmenge in der Beschickung für ein Behandlungsverfahren geeignet ist.

Fig. 1

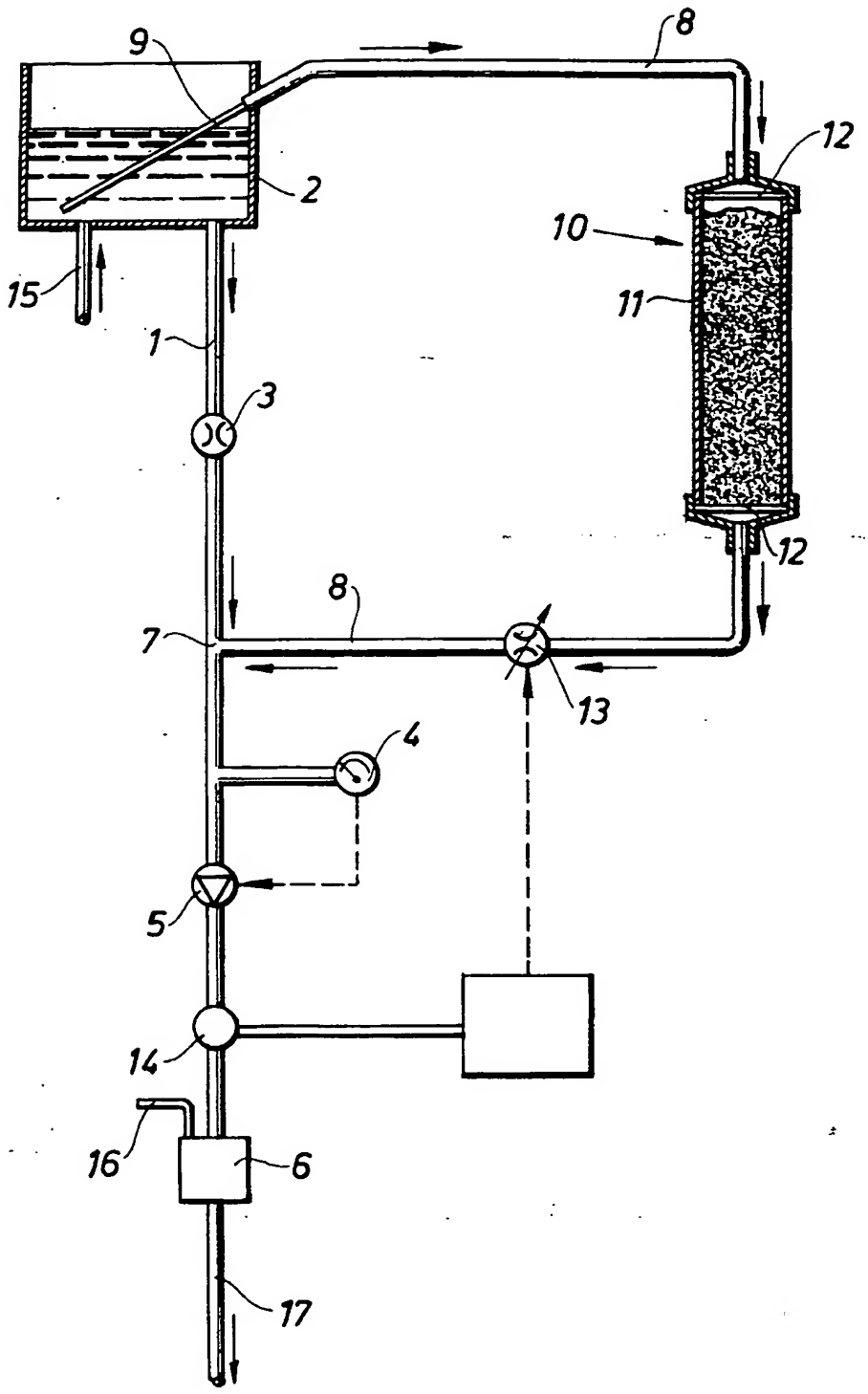

Fig. 2

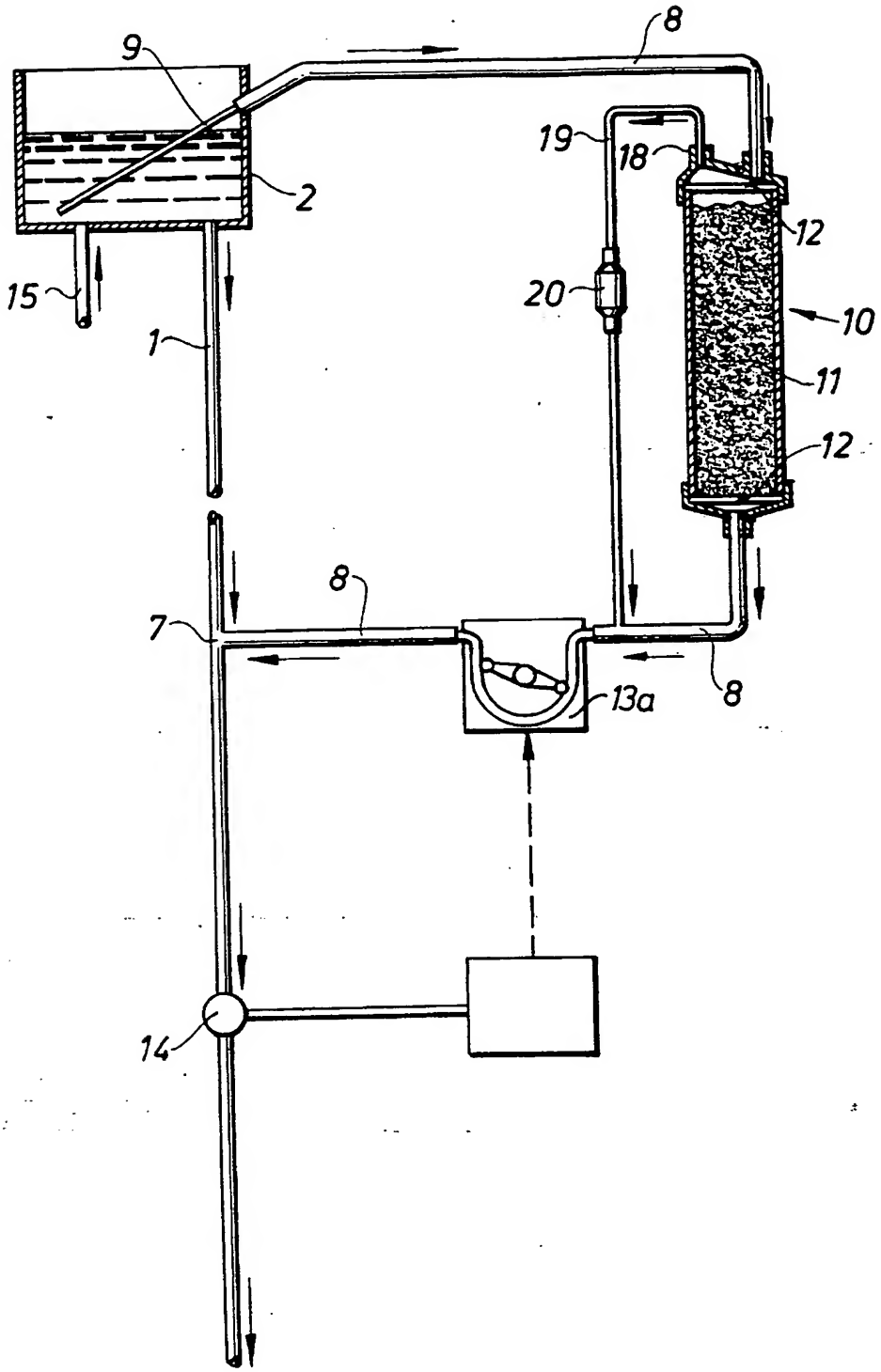

Fig. 3

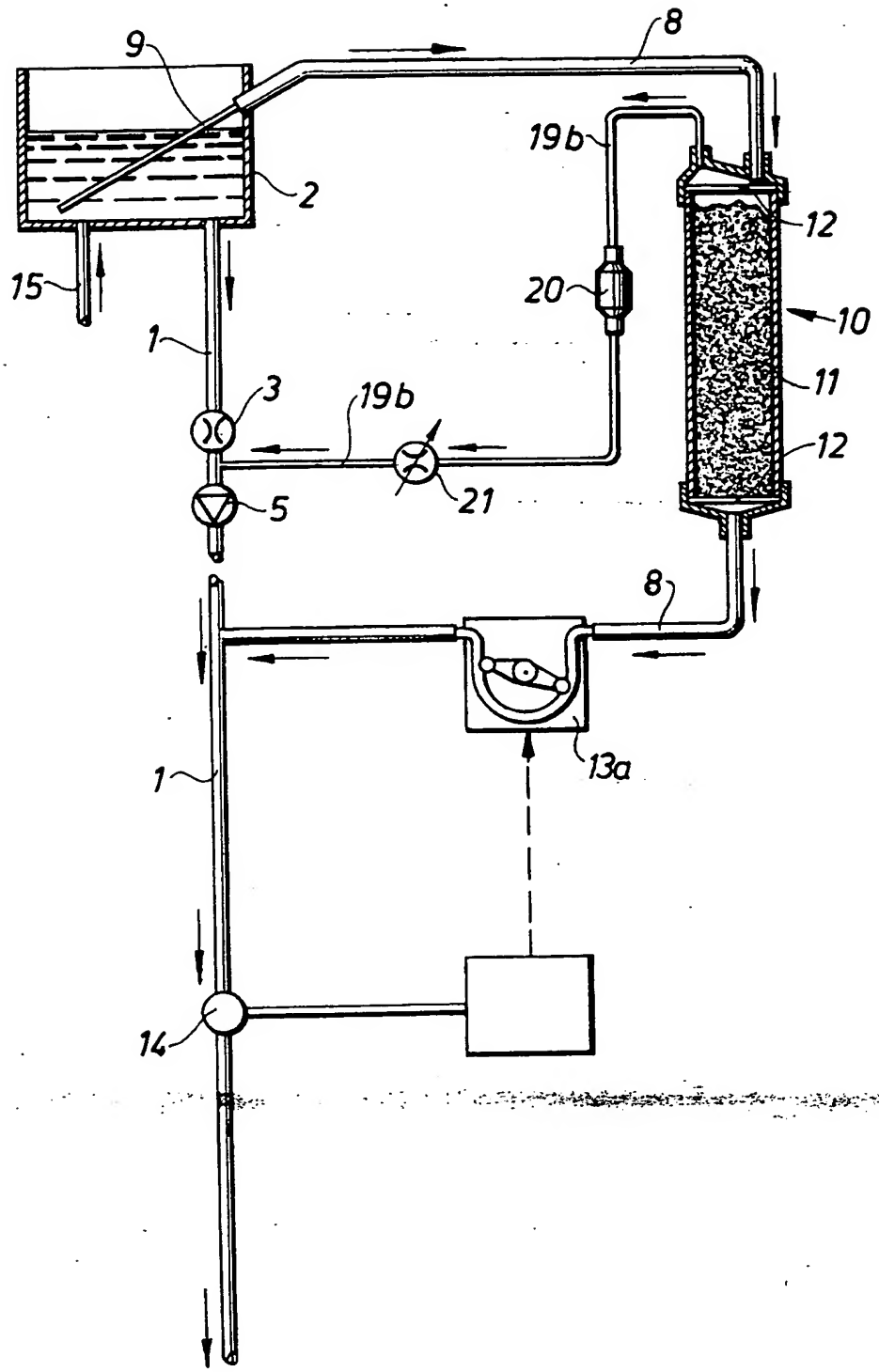

Fig. 4

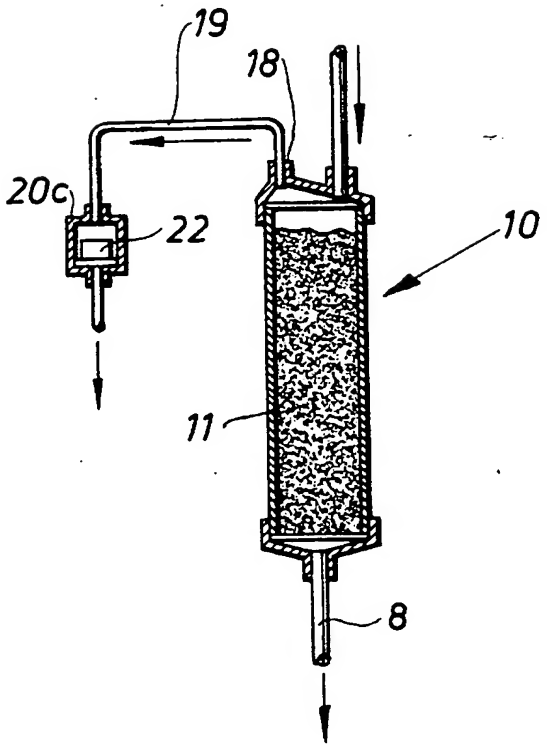

Fig.5

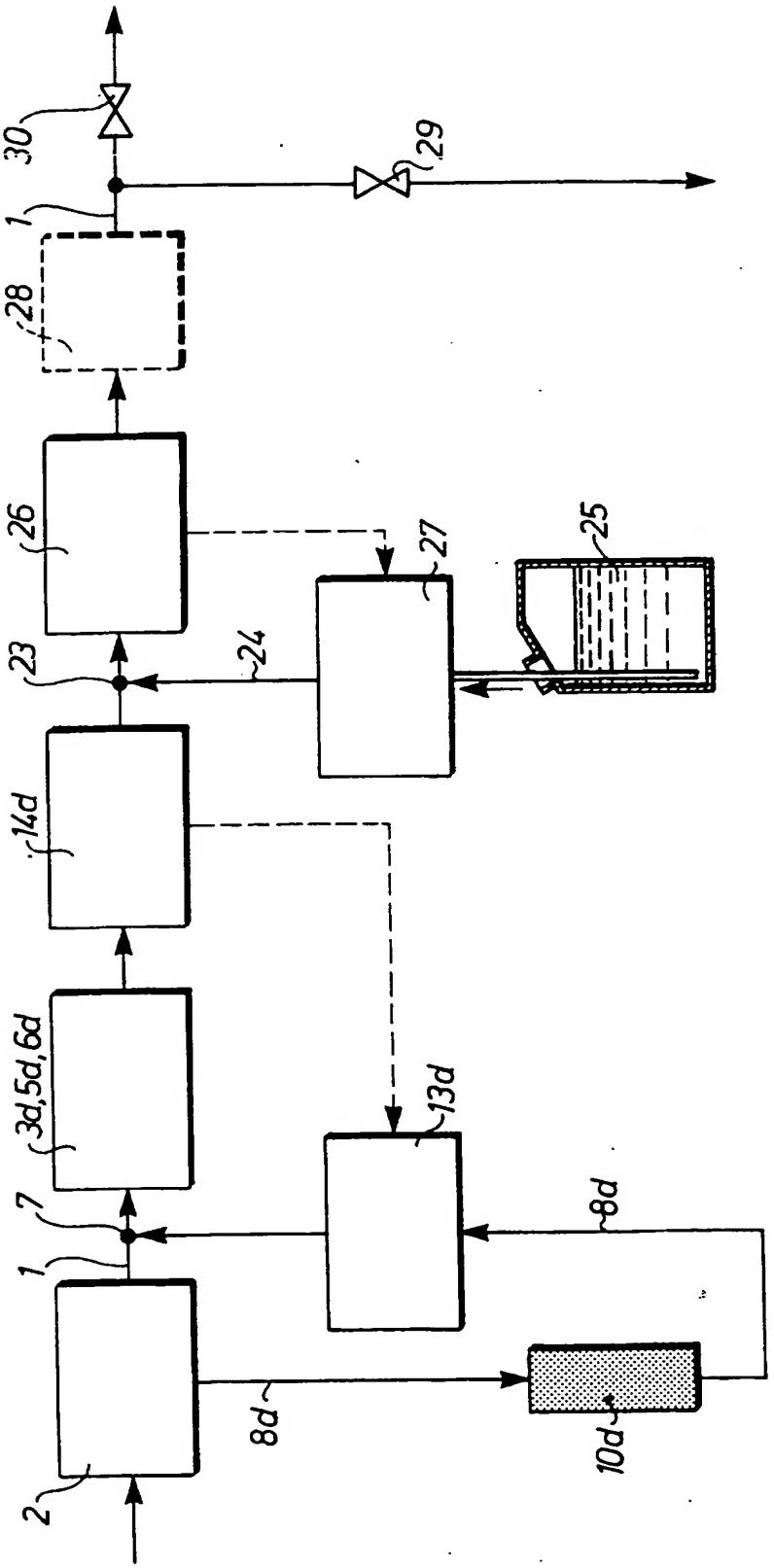

Fig. 6

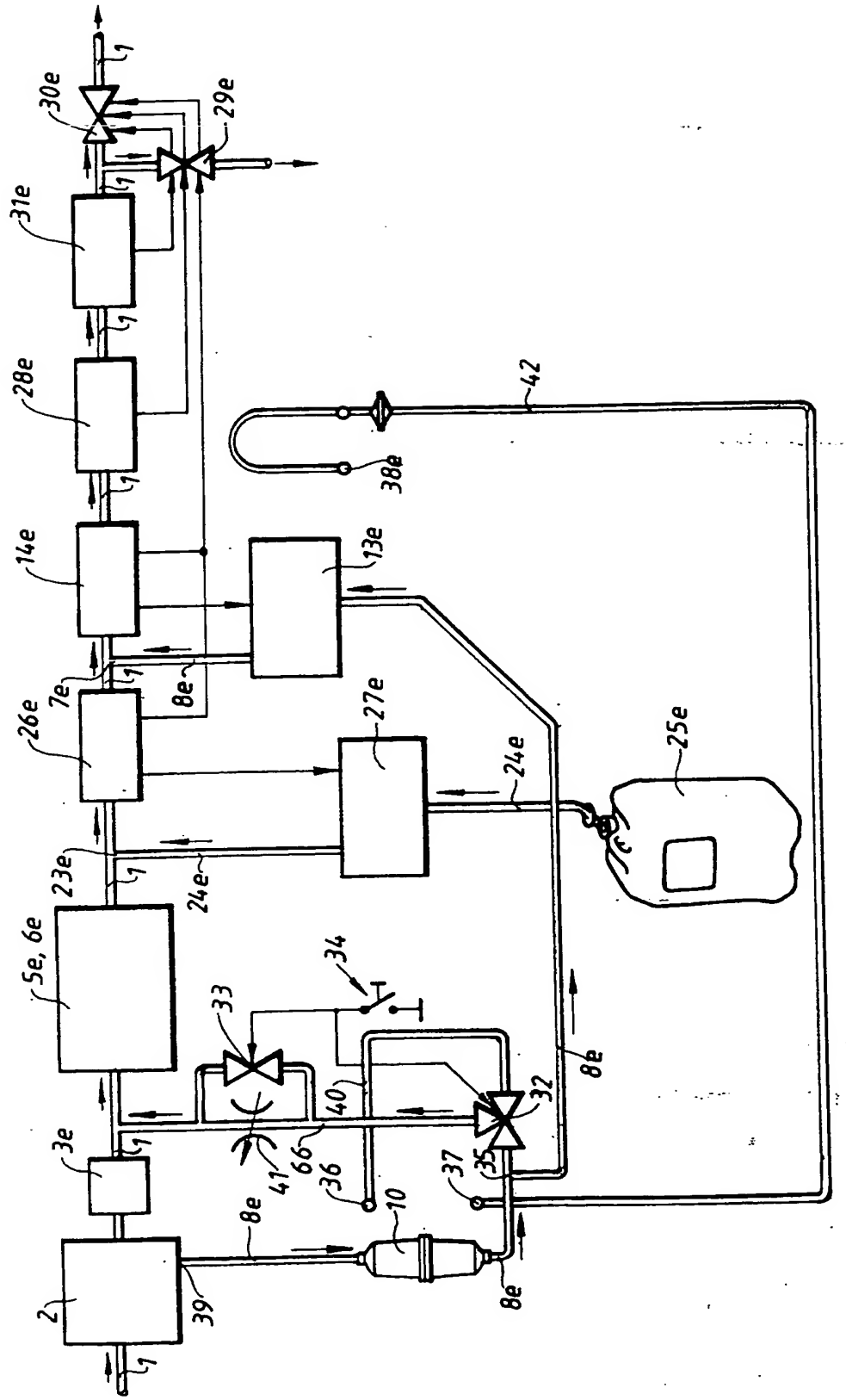
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Fig. 7